UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In Re Bair Hugger Forced Air Warming Products Liability Litigation	**MDL No. 15-2666 (JNE/FLN)**

PLAINTIFFS,

v.

3M COMPANY and ARIZANT

HEALTHCARE, INC.

EXPERT REPORT OF TIMOTHY A. ULATOWSKI

FOR DEFENDANTS

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APPENDICES

I. CREDENTIALS AND EXPERIENCE

I have attached my *curriculum vitae*, detailing my education, academic and professional experience, and professional affiliations, as Exhibit A.

I am an expert on matters concerning medical device regulations, policies, and procedures administered by the Food and Drug Administration (FDA or the Agency). I was awarded a Bachelor of Science degree with honors in 1974 with a major in Microbiology from the Pennsylvania State University. In 1987 I was awarded a Master of Science degree in Physiology with an emphasis in Biomedical Engineering from the Georgetown University School of Medicine in a collaborative program with the Catholic University Department of Engineering. I have additional college credits in computer science from the University of Maryland and Charles County Community College.

I was an employee of the FDA from November 1974 until January 2011. During my 36 plus years of employment with the FDA I held positions of increasing responsibility: First for 7 years in what is now known as the Center for Drug Evaluation and Research, and the remaining years in the Center for Devices and Radiological Health (CDRH). CDRH is responsible for evaluation and clearance or approval of new medical devices, evaluation of medical device clinical investigations, ensuring compliance with medical device laws and regulations administered by the FDA, post-market vigilance of marketed devices, and research on emerging device technologies.

From 1974 until 1978 I held the position of Microbiologist in the National Center for Antibiotic Analysis where I conducted laboratory analyses on antibiotics for regulatory certification purposes. From 1978 until 1980 I held the position of Consumer Safety Officer (CSO) in the Office of New Drug Evaluation (ONDE). While at ONDE I was a product manager for the Anti-inflammatory Drugs Group and I also contributed to the Oncology and

Radiopharmaceutical Drugs Groups. I was the Executive Secretary for the Arthritis Advisory Committee and managed the flow of work and outputs concerning investigational new drug applications (INDs) and New Drug Applications (NDAs). I also was the division lead on major issues such as the Drug Efficacy Study Implementation (DESI) program. In my capacity as a CSO I became expert in drug regulations, policies, and procedures.

In 1980 I joined the Office of New Device Evaluation (NDE), Program Management Group, in the Bureau of Medical Devices (BMD) as a CSO. BMD was soon reorganized and joined with the Bureau of Radiological Health to form the Center for Devices and Radiological Health (CDRH). NDE was renamed the Office of Device Evaluation (ODE).

I was assigned to the Investigational Device Staff in ODE and was responsible for formulating policies and procedures to implement the new Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812, and other new human subject protection regulations, 21 CFR Parts 50 and 56, dealing with informed consent and institutional review boards. I evaluated IDE applications, which are submissions to seek permission from FDA to conduct clinical studies of new devices. I provided opinions to industry and FDA staff regarding custom devices, which are defined in the IDE regulation. I also evaluated and quality controlled the IDE review work of all the divisions in ODE.

In 1988 I was promoted to Director of the IDE staff. In that capacity I was responsible for managing and directing the IDE staff, for making final recommendations on the sufficiency of IDE applications and the reviews of those submissions by FDA staff, and for IDE regulatory compliance in collaboration with the Office of Compliance, CDRH. In this position I was the CDRH expert on IDE, IRB and informed consent regulations, policies and procedures.

Later in 1988 I transferred to the position of Branch Chief, General Hospital Devices, in ODE. As Branch Chief I managed and directed the branch staff and was a primary reviewer of IDE applications, Premarket Notification Submissions (510(k)s), Premarket Approval Applications, new product labeling, medical device reports (MDRs) and other types of regulatory submissions under the purview of my branch. My branch evaluated products classified by FDA under 21 CFR Part 880, General Hospital Devices. The products in this classification regulation included, for example, drug infusion devices, administration sets and intravascular catheters. In this position I was an expert in premarket submissions and medical device reporting regulations, policies and procedures. Also, from this appointment forward until the end of my FDA career I was classified by the government as a Supervisory Biomedical Engineer based on my education, training, and experience.

In 1991, I was promoted to the position of Associate Director for General Devices in ODE. The scope of my responsibilities expanded to include the premarket evaluation of surgical devices classified under 21 CFR Part 878 as well as the previously assigned general hospital products. I had broader influence on guidance, policies and procedures spanning the entire ODE. I formulated guidance, policies and actions on many significant new products such as medical lasers and computerized medical systems.

In 1996 I was promoted to the Director, Division of Dental, Infection Control and General Hospital Devices in ODE. In this position I assumed responsibility for more product areas and associated regulatory submissions including devices intended to mitigate the risk of infection (e.g., surgical drapes, gowns, sterilizers, disinfectants, gloves). During my tenure as Director I interacted with government agencies like CDC, NIOSH, EPA, and OSHA and

professional organizations like APIC, AMA, ADA and others on many infection control practice issues.

For over 15 years I participated as a member of various national and international standards committees charged with creating standard specifications for devices, standard test methods to evaluate the performance of devices, and healthcare facility procedures for the users of devices.

I was a representative of the US FDA on the Global Harmonization Task Force (GHTF). The GHTF, which has now transitioned to the International Medical Device Regulators Forum, was tasked with creating globally unified procedures concerning (1) the evaluation of new medical devices, (2) the auditing of manufacturing facilities, (3) the quality system criteria upon which devices are designed and manufactured, (4) the postmarket vigilance of devices, and (5) the clinical assessment of devices. The GHTF consisted of regulators and industry from the European Union, Japan, Canada, Australia and the US. I eventually became the head of the US delegation to the GHTF and a member of the GHTF Steering Committee. In this capacity I interacted with senior level regulators from the GHTF member countries and regulators from many other parts of the globe. During my time on the GHTF I became very familiar with the medical device regulatory procedures used in all the GHTF member countries and in other countries.

I was the co-chair of the FDA committee that created the existing standards program in CDRH. The CDRH standards program evaluates national and international medical device related standards to determine which standards FDA should "recognize" and utilize as means to support device development, manufacturing and premarket submissions. During this time I also

wrote the first FDA guidance documents on infusion pumps and accessories, infusion ports, sterilizers, chemical germicides and labeling of devices intended for reuse.

In 2003 I was promoted to Director, Office of Compliance, CDRH. As the office Director I supervised a large staff that was responsible for ensuring compliance with the medical device, radiological health, and human subject protection laws and regulations administered by FDA. I had many duties, such as the following: determining the work plan for inspections for the forthcoming year and allocating resources for the various aspects of that plan; identifying and prioritizing by risk the manufacturing facilities to be inspected; evaluating and making final agency determinations on actions to be taken based on inspection findings 483s related to the Quality System, correction and removal, bioresearch, and medical device reporting regulations; evaluating various forms of information to identify whether field actions by manufacturers were necessary and communicating with manufacturers regarding those decisions; creating risk management strategies to mitigate emerging public health issues; evaluating manufacturer manufacturing and risk management documents; evaluating advertising, labeling and promotional literature for compliance with labeling and other regulations or statutes; serving as Co-Chair of the FDA Device Field Committee, which is composed of chief inspectors and senior compliance officers; and managing actions related to import/export and registration regulations and statutes. In this position, I was an expert in FDA law and regulations concerning medical devices.

I transitioned to the position of Senior Advisor for Enforcement in October 2010 in anticipation of my retirement and to allow for an orderly succession of leadership. During the last four months of my FDA career, I led a team formulating strategies in advance of user fee

reauthorization, and I provided expert advice to senior FDA leadership on potential changes to premarket and compliance programs.

During my employment with FDA, I received virtually every type of award FDA can bestow including the prestigious Distinguished Career Service Award, Award of Merit, and Commendable Service Award. I received numerous other individual and team member awards as well as yearly performance bonuses. I maintained my management and regulatory expertise during the course of my FDA career by attending numerous professional meetings, courses and seminars. I attended the George Washington School of Law where I studied Food and Drug law. I was frequently the keynote speaker or major participant at regulatory and professional conferences here and abroad such as those held by the Food and Drug Law Institute, Regulatory Affairs Professional Society, and the American Medical Association. I remain current on FDA matters through my memberships with the Regulatory Affairs Professional Society (RAPS) and the FDA Alumni Association, attendance at professional meetings, and surveillance of FDA-related web sites and literature.

I continue to provide training on FDA and international regulation of medical devices to international regulators as an invited speaker at regulatory forums sponsored by the US FDA, the US Department of Commerce, and the US Department of State. According to the Department of Commerce the US FDA has designated me a "trusted speaker" on medical device regulations and procedures.

I currently am an independent consultant and most of my work is contracted through consulting firms such as NSF Health Sciences and NDA Partners LLC. I maintain a registered business in the State of Virginia and the County of Fairfax, Virginia under the name Ulatowski Consulting, LLC.

II. DISCLOSURES

The customary professional fee charged for my consulting time and testimony by NSF Health Sciences in connection with this litigation is $500 per hour. A list of documents I have reviewed and relied upon in the course of my evaluation of the present matter is attached as Exhibit B. I may use all or parts of these materials, or summaries and depictions thereof, as exhibits or demonstrative aids to summarize, support or explain my testimony in this matter. In addition, my opinions are based on my knowledge and experience of FDA regulation of healthcare products, including all applicable laws, regulations, guidance, and policies. I did not rely on any commercial confidential or trade secret information obtained during the course of my employment with FDA in forming my opinions. My previous trial and deposition testimony from the last 5 years is listed in Exhibit C. I have no publications within the past 10 years.

III. BACKGROUND

1. Overview of the Regulation of Medical Devices

FDA regulates medical devices under the authority of the Federal Food, Drug, and Cosmetic Act (the Act). This authority over medical devices was granted to FDA on May 28, 1976, the enactment date of the Medical Device Amendments of 1976. The objective of FDA device regulation is to provide the American public reasonable assurance of safety and effectiveness of all medical devices introduced into interstate commerce.

Title 21 of the Code of Federal Regulations (CFR) codifies the general and permanent rules established by FDA for medical products subject to the Act. Parts 800 to 1299 pertain to medical device requirements including design, manufacturing, marketing authorization, investigational use, classification, post-marketing requirements, and compliance with current Good Manufacturing Practice (cGMP) requirements for finished devices.

FDA periodically issues guidance that represents current thinking by the Agency on a subject. This can take the form of formal guidance documents issued by the Agency, or more informal communication, *e.g.*, teleconferences or face-to-face meetings. FDA guidance does not establish legally enforceable responsibilities, but may cite specific regulatory or statutory requirements.

The basic framework for FDA regulation of medical devices, and the statutory basis for providing "reasonable assurance of safety and effectiveness" of medical devices,[1] rests on a risk-based classification system. Accordingly, FDA has classified all devices into one of three regulatory classes: Class I (general controls), Class II (special controls), or Class III (premarket approval). The class of a device determines the regulatory and statutory controls needed to provide reasonable assurance of safety and effectiveness of that device.

Class I devices tend to be simple devices that present minimal potential for risk and require the least amount of regulation by the Agency. For Class I devices, the general controls of the Act are considered sufficient to provide reasonable assurance of safety and effectiveness.[2] General controls include provisions against adulteration and misbranding, premarket notification[3], good manufacturing practices, establishment registration, and device listing. Examples of Class I devices are stethoscopes, surgical gloves, medical bed linens, hand-held surgical instruments, examination gloves, and elastic bandages.

Class II devices tend to be more complex than Class I devices. They are subject to general controls, but may also be subject to special controls, which together provide reasonable

[1] 21 USC §360c(a).

[2] 21 CFR §860.3(c)(1).

[3] Many Class I and several Class II devices are exempt from premarket notification and portions of the Quality System Regulation.

assurance of safety and effectiveness.[4] Special controls for any given device must be codified by regulation and may include such requirements as conformity to specified standards, specific post-market surveillance obligations, a patient registry, product-specific guidance, and any other actions that FDA determines are necessary to assure reasonable safety and effectiveness. The Bair Hugger Forced Air Warming device is a Class II device.

Class III devices are products that are life supporting or life sustaining or may present a potential for unreasonable risk of illness or injury and general and special controls alone are insufficient to assure safety and effectiveness.[5] Class III devices are subject to general controls and are subject to premarket approval, except for a period of time for certain pre-1976 Class III devices. To market a Class III device subject to premarket approval, FDA requires submission and approval by FDA of a Premarket Approval Application (PMA).

FDA has promulgated regulations under 21 CFR §§860-892 detailing the class of numerous device types grouped by medical systems, e.g., cardiovascular, ophthalmic. When a person intends to market a new device he can compare his new device to the classification listings to identify the type and class for his new device. The class of the device determines the regulatory path to the market.

In general, regulations require that a person notify FDA of his intent to market a potential new Class I or II device at least 90 days before he proposes to introduce the device into commerce. A person notifies FDA by submitting a premarket notification submission, also commonly referred to as a 510(k) submission (aka a "510(k)"). Premarket notification submissions are subject to the requirements of 21 CFR §807, Subpart E - Premarket Notification

[4] 21 CFR §860.3(c)(2).

[5] 21 CFR §860.3(c)(3).

Procedures. Almost all Class I devices are now exempt from the requirement to submit a 510(k) as are some Class II devices.

A 510(k) submission, if required, is the evidentiary basis for FDA to determine the final classification of a new device, i.e., Class I, II, III. Section 510(k) of the Act requires that the person submitting the 510(k) demonstrate from the data and information provided to FDA in the 510(k) that the new device is "substantially equivalent" to a legally marketed Class I or II device, also referred to as a "predicate device."[6] If a person considering marketing a new device cannot identify a legally marketed predicate device then a 510(k) submission is not viable and the device is classified as Class III.[7]

According to the Act and regulations, the term "substantially equivalent" means with respect to the new device being compared to a predicate device that the new device has (1) the same intended use as the predicate device; and (2) it has the same technological characteristics as the predicate device; or (3) has different technological characteristics and the information submitted to demonstrate that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and effective as a legally marketed device, and does not raise different questions of safety and effectiveness than the predicate device.[8]

[6] A person submitting a 510(k) may rely on more than one predicate device for purposes of establishing substantial equivalence and also include information on specific scientific or engineering aspects of a marketed "reference device" to support the safety and effectiveness of the new device.

[7] There is a statutory process called "de novo" that may be used to classify a low to moderate risk device where there is no predicate into Class II or I. This process is not relevant to knee implants. FDA may assist in identifying an appropriate predicate during the course of a 510(k) review, at a pre-submission meeting, or more formally in response to correspondence.

[8] 21 USC §360c(i)(1)(A) and 21 CFR §807.100(b)(ii)(B).

FDA has interpreted the statutory and regulatory meaning of substantial equivalence and created guidance on the method used by FDA to determine substantial equivalence.[9] According to the guidance, a new device must have the same intended use as the predicate device and technological characteristics to be found equivalent or the different technological characteristics do not raise different questions of safety and effectiveness. FDA will assess the different characteristics based on submitted performance data to determine whether the new device is equivalent.

The three types of 510(k)s are traditional, special, and abbreviated.[10] The traditional 510(k) includes information and test data addressing all the submission requirements listed in the 510(k) regulation. Abbreviated 510(k)s, although also containing information addressing all the submission requirements, include declarations or references to FDA-recognized standards used in the design and/or testing of the device. Special 510(k)s is a submission made by a manufacturer for a change to one of their marketed devices and includes descriptive information and a concise summary of design control activities focused on the specific change.

If FDA finds a new device substantially equivalent to a legally marketed predicate device the new device is classified in the same regulatory class as the predicate, and unless it is a Class III device and a PMA is required, FDA issues an order authorizing its commercial distribution.

A device that was in commercial distribution prior to May 28, 1976, (called a pre-amendments device) that FDA classified as a Class III device, and those new devices found substantially equivalent to this device by means of a 510(k) submission may continue to be

[9] FDA Decision Flowchart, 2014 revised guidance but same flowchart logic, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf.

[10] The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm.

marketed until FDA, by final administrative order,[11] requires the submission and approval of a PMA for these pre-amendments Class III devices.[12]

So, it is the classification and pre-amendments status of a device that dictates the form and manner of submission to FDA, i.e., 510(k) or PMA, for marketing authorization. The manufacturer may not seek to submit a PMA when a 510(k) is viable.

Changes to legally marketed devices subject to premarket notification requirements are subject to strict controls. A new 510(k) for a legally marketed device is required for changes or modifications that could significantly affect the safety or effectiveness of the device.[13] As such, the manufacturer must carefully assess every change or modification to a legally marketed device to determine if it is required to be the subject of a new 510(k) submission.

FDA developed a guidance document to outline the criteria that companies should consider when making decisions to submit – or not to submit – 510(k) notifications for modified Class I, II, or pre-amendments Class III devices not yet subject to premarket approval. In January 1997, FDA issued the guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device."[14] This guidance document is still in effect today and has not been modified. It is relied on by industry in making decisions to submit a new 510(k) notification, and by FDA in assessing individual company decision-making in this regard.

The guidance document generally addresses virtually all types of changes that may occur with medical devices, including labeling changes, technology/engineering or performance changes, and materials changes. The document outlines the systematic evaluation process for

[11] Process changed from a final regulation to an administrative order per FDASIA (126 Stat. 156).

[12] Call for PMAs, 21 CFR §860.132. In response to the call for a PMA any person can also submit a petition to reclassify the device from Class III to another class.

[13] 21 CFR §807.81(a)(3).

[14] US Food and Drug Administration, Deciding When to Submit a 510(k) for a Change to an Existing Device (#K97-1), www.fda.gov.

companies to use when considering such changes and their regulatory impact, and also provides a framework for the documentation of decisions reached. The guidance document defines common terms, discusses the decision logic that companies should use, presents device-specific examples, and provides a series of flowcharts that clearly outline the thought process to be applied and the outcomes. Companies are expected, although not required, to follow this guidance when determining whether a new 510(k) is necessary for a product change.

Changes to product labeling for Class I and II or pre-amendments Class III devices not yet subject to premarket approval require clearance of a new 510(k) submission by FDA if the intended use is changed or the change is of a type recommended as requiring a new 510(k) in the aforementioned guidance. This also applies to 510(k)-exempt Class I and II devices. Labeling changes to marketed devices intended to enhance safer or more effective use are examples of labeling changes that typically do not require clearance.

Device manufacturers worldwide employ a quality system to help ensure that their finished devices are safe and effective. In the US the current good manufacturing process requirements are set forth in the Quality System (QS) regulation.[15] These requirements govern the methods, facilities and controls used for device design, manufacture, packaging, labeling, storage, installation, and servicing. The regulations specify that each manufacturer shall establish and maintain a Quality System that is appropriate for the specific device(s) designed or manufactured.[16] Certain Class I devices are not subject to all of the QS regulation requirements.

[15] 21 CFR Part 820.

[16] 21 CFR §820.5.

Medical device manufacturers are a diverse group. Many are considered small manufacturers.[17] The QS regulation provides flexibility to companies to establish procedures that work best for their size and for the specific products they manufacture, and their particular intended use. Accordingly, there is no requirement that every company design, manufacture, or market its products in the same manner.

2. FDA maintains broad enforcement authority during the life cycle of a medical device.

The "life cycle" of a device is a term to characterize the period from the point where the product is conceived and the design process begins until the device is no longer on the market.[18] The FDA has in its armamentarium many administrative, advisory, judicial and recall options to enforce the law and regulations during the life cycle of a device, based upon the Act[19] and regulations, as described in FDA regulatory procedures.[20] FDA has seizure, civil money penalty, temporary restraining and injunctive authority. FDA may require a recall of a device. FDA inspects facilities and may issue warning letters based on the inspection,

If at any point during the review of a marketing submission the FDA suspects that the content of the submission, or any other information from a manufacturer, is misleading or fraudulent, it can conduct an unannounced inspection of the submitter's establishment to examine all records FDA deems relevant. If FDA concludes as a result of its inspection that action is required, it may impose safeguards, such as the Application Integrity Policy, which can place the manufacturer's pending premarket submissions in jeopardy.

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[17] FDA has a Division of Small Manufacturers, International and Consumer Assistance to aid small manufacturers in complying with FDA rules and regulations.

[18] FDA has previously coined the term "Total Product Life Cycle" to describe the stages of product marketing and applied regulatory controls. The term "life-cycle" is also used in ISO 13485.

[19] 21 USC §§331-337.

[20] Regulatory Procedures Manual, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176446.htm.

3. FDA cleared or approved prescription labeling is the primary regulatory source of information for physicians on the safe and effective use of medical devices.

Labeling for a prescription medical device such as the Bair Hugger must include "indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented."[21] Physicians may also become aware of information concerning a device through training, professional meetings, from other doctors and by other means.

Practitioners licensed by law to have in their possession and to use a prescription device must supervise its use.[22] The regulations do not provide for delegation or transfer of a practitioner's responsibility to be informed regarding the directions for use of a prescription device.

FDA evaluates labeling in marketing applications when it reviews the application. After devices are cleared or approved, manufacturers may not make significant labeling changes without FDA clearance or approval.[23]

4. FDA Review of 510(k) marketing applications is rigorous.

In my opinion there are six important factors in the FDA review of a marketing application, i.e., a 510(k) or PMA, and those are the experience and training of the front line review staff, the contents of the submission, the knowledge base of the review staff on the same

[21] 21 CFR §801.109.

[22] Id.

[23] 21 CFR §807.81(a)(3) and 21 CFR §814.39.

type of product, databases and information sources available to the review, collaboration between review staff, and the supervisory review process.

Based on my 31 years of experience evaluating IDEs, PMAs and 510(k)s I know that the FDA staff is very well trained to review submissions. They come to the FDA with scientific, technical or clinical degrees, many of those advanced degrees, and with advanced experience in engineering, toxicology, medicine and other disciplines.

The FDA review staff are trained how to review the entire contents of a marketing application and to formulate legally sound recommendations based on those reviews. Seasoned FDA experts mentor new FDA reviewers and those experts validate the new reviewer's work until the new reviewer can independently review their assigned portions of submissions. The reviewers utilize guidance and checklists to make sure the submissions are complete and to guide them in their decision-making. Their reviews are documented for the record. FDA conducts frequent training to keep skills at the highest level and those skills are assessed in performance reviews.

The FDA front line reviewers or their mentors have already evaluated prior 510(k)s, IDEs and PMAs for devices that are very similar to the one in the new marketing application under review. For example, the same review team at FDA will be assigned to evaluate an IDE, PMA and 510(k)s for total hip devices. Due to their training, experience, and knowledge of prior submissions, the review staff expect to see specific descriptive information and test data submitted in a marketing application. If information is lacking FDA can request any information it deems necessary to complete its evaluation.

It is the job of the FDA reviewers to thoroughly assess a submission, to uncover areas of significance whether or not those areas are "highlighted" by the submitter, to pose questions on those significant issues, and have them resolved before the review can be completed.

The FDA review is independent and thorough. The FDA drives the review process, not the applicant. While the applicant may seek clarification of FDA's requests or consideration of alternative scientific/clinical/engineering data to respond to FDA's requests ultimately FDA is the final arbiter of what data and information it needs in order to render a final decision.

Databases on adverse effects, recalls, inspections, design and test standards, published literature, and prior submissions, to name a few, are at an FDA reviewer's immediate disposal. FDA reviewers are instructed how to examine these databases and apply their findings in order to identify safety or effectiveness issues that may impact the review of a new marketing application.

No reviewer is isolated from the experience and skills of all other FDA review staff and external advisory committee experts.[24] For any given submission a reviewer may rely on teams of experts within FDA, such as an engineering team within the device Center, to advise him or her on any scientific or medical aspect. Thus, the knowledge base for review of a submission is multiplied by the combined expertise within FDA.

At least two levels of supervisory reviews take place before a final decision on a marketing application is made. The supervisors ensure that the 510(k), PMA or IDE was reviewed according to policy and procedure and that the conclusions are scientifically and

[24] Persons nominated as scientific advisory committee members must be technically qualified experts in their field (e.g., clinical medicine, engineering, biological and physical sciences, and biostatistics) and have experience interpreting complex data. Candidates must be able to analyze detailed scientific data and understand its public health significance. See http://www.fda.gov/advisorycommittees/aboutadvisorycommittees/committeemembership/applyingformembership/default.htm.

medically sound. The supervisors may seek input from experts in FDA in order to render a decision.

Given these six factors, every marketing submission is thoroughly reviewed in its entirety. In addition to the information in each submission, FDA also has a deep body of information on the type of device under review. FDA staff have a commanding knowledge of this information and they understand the history and scientific/medical context of the type of product being evaluated. All of this knowledge and information is brought to bear by the reviewers when evaluating a submission.

IV. OVERVIEW OF THE BAIR HUGGER TEMPERATURE MANAGEMENT UNIT MODELS 505 AND 750 AND OTHER TEMPERATURE MANAGEMENT SYSTEM SUBMISSIONS TO FDA

The devices associated with this litigation are collectively identified in the Master Long Form Complaint of August 24, 2016, as the "Bair Hugger Forced Air Warming device."[25] Based on the Complaint the model of the Bair Hugger allegedly used on each Plaintiff is not stated. The Complaint refers to the Models 505, 750 and 775. Currently, 3M promotes on its web site only the Bair Hugger Model 775.[26]

Based on the labeling the Models 505, 750 and 775 the Bair Hugger brand Total Temperature Management System consists of a Bair Hugger forced-air temperature management unit and disposable components.[27] These are prescription use only devices.

[25] Complaint, Paragraph 1.

[26] 3M Bair Hugger Warming Units, http://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Bair-Hugger-Warming-Units?N=5002385+3293316253&rt=rud.

[27] 775:http://multimedia.3m.com/mws/media/798454O/model-775-operators-manual-english.pdf, 505: http://multimedia.3m.com/mws/media/798375O/operators-manual-english.pdf, and 750:

The Bair Hugger total temperature management system is intended to treat and prevent hypothermia per the Indications in labeling. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The system can be used with adult or pediatric patients.

The 500 and 700 series devices are designed to operate safely with only 3M Patient Warming components.[28] The 500 and 700 series devices have been designed to operate with only Bair Hugger blankets, Bair Paws gowns and the 241 Body Fluid Warming Set.[29]

The FDA 510(k) submission history of the marketed compatible Bair Hugger blankets and Fluid Warming Set for the Model 505 and 750 are listed in the Model 750 submission to FDA as follows:[30]

[28] See for example, http://multimedia.3m.com/mws/media/824193O/3m-bair-hugger-therapy-accessories.pdf and 3MBH00042837.

[29] 3MBH00042837 and Model 775 labeling, http://multimedia.3m.com/mws/media/798454O/operators-manual-english.pdf; Model 505 labeling, http://multimedia.3m.com/mws/media/798375O/operators-manual-english.pdf; Model 750 labeling, http://multimedia.3m.com/mws/media/798412O/operators-manual-english.pdf; blankets http://multimedia.3m.com/mws/media/768611O/breadth-of-line.pdf; Bair Paws gowns, http://www.3m.com/3M/en_US/company-us/all-3m-products/?N=8707795+5002385+8711017&Ntt=bair+paws&LC=en_US&co=cc&gsaAction=scBR&rt=rs&type=cc; 241 Fluid Warmer, http://www.3m.com/3M/en_US/company-us/all-3m-products/?N=8707795+5002385+8711017&Ntt=241+fluid+warmer&LC=en_US&co=cc&gsaAction=scBR&rt=rs&type=cc.

[30] 3MBH00047012.

Bair Hugger® Blankets- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same blankets as found in the predicate device, the Model 505 Total Temperature Management system. These blankets, listed below, are currently manufactured and marketed by Augustine Medical.

- Model 522 Upper body blanket (K903360)
- Model 525 Lower body blanket (K903360)
- Model 540 Torso blanket (K921165)
- Model 537 Small lower body blanket (K950416)
- Model 300 Full body blanket (K873745)
- Model 536 (K920432)
- Model 530 (K913734)
- Model 305 Chest access blanket (K920265)
- Model 315 Multi-access blanket (K950416)
- Model 310 (K950416)
- Model 650 (K952864)
- Model 655 (K952864)
- Model 610 Full body surgical (K950432)
- Model 110 Outpatient (K960167)
- Model 630 Sterile cardiac access (K964673)
- Model 645 cardiac (K913734)
- Model 555 pediatric full access (K913734)
- International white blankets: Models 42268 (K903360), 42568 (K903360), 40068 (K873745), and 44068 (K921165)

Model 241 Fluid Warming Set- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same 241® Fluid Warming Set (K933726) as found in the predicate device, the Model 505 Total Temperature Management system. The 241 Fluid Warming Set is currently manufactured for and marketed by Augustine Medical.

There are fifteen 510(k) submissions listed on FDA's web site using "Bair Hugger" as a search term.[31] There are four more using "Arizant" as the search term. There is more than one device listed for certain 510(k)s. Line additions to device families can be marketed without

[31]FDA web site listing of 510(k)s for "Bair Hugger", searched 4/19/17, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&Center=&Panel=&ProductCode=&KNumber=&Applicant=&DeviceName=Bair%20Hugger&Type=&ThirdPartyReviewed=&ClinicalTrials=&Decision=&DecisionDateFrom=&DecisionDateTo=04%2F19%2F2017&IVDProducts=&Redact510K=&CombinationProducts=&ZNumber=&PAGENUM=10&SortColumn=dd%5Fdesc.

resubmission to FDA.[32] I also independently confirmed the 510(k) for the Model 110 noted above but not in the FDA search listing below. The FDA web listings are as follows:

510(k) Listing for Bair Hugger devices

Device Name	Applicant	510(K) Number	Decision Date
Modification To:bair Hugger Temperature	Arizant Healthcare Inc.	K053645	03/09/2006
Bair Hugger Temperature Management Syste	Arizant Healthcare Inc.	K041686	06/30/2004
Bair Hugger Temperature Management Syste	Augustine Medical, Inc.	K021473	07/09/2002
Augustine Medical Bair Huuger, Model 750	Augustine Medical, Inc.	K001149	09/06/2000
Bair Hugger Blood/fluid Warmer	Augustine Medical, Inc.	K973741	04/30/1998
Bair Hugger Model 630 Cardiac Blanket	Augustine Medical, Inc.	K964673	06/26/1997
Bair Hugger Model 655 Blanket	Augustine Medical, Inc.	K952864	09/12/1995
Bair Hugger Model 600 Unit, Blankets	Augustine Medical, Inc.	K950416	08/29/1995
Modification Of Bair Hugger Patient Warm	Augustine Medical, Inc.	K933726	01/28/1994
Bair Hugger Torso Blanket - Arms In Mode	Augustine Medical, Inc.	K921165	08/06/1992
Bair Hugger Cub Blanket- Short Model 536	Augustine Medical, Inc.	K920432	06/18/1992
Bair Hugger Patient Warming System	Augustine Medical, Inc.	K920265	03/27/1992
Bair Hugger(r) Patient Warm Syst/baby Wa	Augustine Medical, Inc.	K913734	10/23/1991
Bair Hugger(r) Patient Warming System-mo	Augustine Medical, Inc.	K903360	08/14/1990
Bair Hugger(tm) - Patient Warming System	Augustine Medical, Inc.	K873745	11/06/1987

[32] A new 510(k) is needed for a new device and when the device to be introduced is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use, 21 CFR §807.81(a).

3m Spoton Temperature Monitoring System	Arizant Healthcare Inc.	K120412	05/30/2012
Ranger Rapid Flow Blood/fluid Warming Sy	Arizant Healthcare Inc.	K082217	10/06/2008
Ranger Irrigation Fluid Warming System	Arizant Healthcare Inc.	K060939	06/26/2006
Bair Paws Temperature Management System	Arizant Healthcare Inc.	K060865	04/24/2006
Modification To:bair Hugger Temperature	Arizant Healthcare Inc.	K053645	03/09/2006
Bair Hugger Temperature Management Syste	Arizant Healthcare Inc.	K041686	06/30/2004

Arizant also introduced nonsignificant device model additions by documenting them as a "letter to file." Such additions include, for example, the Models 500OR and 775.[33]

V. SURGICAL SITE INFECTION ALLEGATION IN THE COMPLAINT

The Master Long Form Complaint filed August 24, 2016, alleges in Paragraph 20 "Because of Defendants' actions and inactions, Plaintiffs were injured due to the use of the Bair Hugger, which has caused and will continue to cause bacteria to enter the surgical site, resulting in a dramatic increase in the rate of periprosthetic joint infections among all patient populations. These infections have caused Plaintiffs surgical debridement, premature prosthetic replacement, extended hospital stays, and amputations." In Paragraph 17 the Complaint alleges "At a minimum, Defendants should have warned patients and healthcare providers of the known risk inherent in using the Bair Hugger in orthopedic surgeries."

VI. PURPOSE OF MY REPORT

I was asked to address the allegations concerning regulatory issues in the Master Long Form Complaint and in the report of Yadin David, Ed.D., P.E., C.C.E. entitled "Hazard Analysis Report: Bair Hugger Patient Warming System." I also respond, from a regulatory perspective, to conclusions in the Plaintiffs Memorandum of Law in Support of Motion for Leave to Amend

[33] "Letter-to-file" changes are not described in the 510(k) regulation but are part of the required documentation of design change provisions of the Quality System regulation, 21 CFR 820.30(i). See 3MBH00501669-00501683 for the Model 500OR and 3MBH00501890-00501957 for Model 775 letters to file. Model 500 510(k) submission is K903360.

Master Long Form and Short Form Complaints to Add Claim for Punitive Damages filed April 21, 2017.

VII. METHODOLOGY AND OPINIONS

In forming my opinions, I employed methodologies consistently used by health care companies and regulatory authorities to address and evaluate post-approval safety data, risk reduction strategies and labeling obligations. These methods are also consistent with those utilized by me, the sole member of Ulatowski Consulting, LLC, in the conduct of my assignments with both U.S. and international health care clients manufacturing medical devices including preparation of regulatory submissions and post-market efforts, preparation of regulatory and scientific protocols, labeling and other risk mitigation evaluations. My opinions are also predicated upon the Food, Drug, and Cosmetic Act, my numerous interactions with the Federal Trade Commission on device labeling and promotion, the Code of Federal Regulations, Federal Registers, and industry practices and standards.

My participation in this litigation and the development of the opinions enclosed herein follow an extensive review process. As described earlier, I possess extensive experience in the medical device industry and draw on this experience in conducting my tasks under the auspices of Ulatowski Consulting, LLC, including the reviews provided herein.

As described, I have performed a thorough and integrated review of the publicly available information and regulatory documents, including those produced during discovery, identified in this report and listed in Exhibit B. I analyzed those documents for their relevance. The employed methodology also included a review of the production documents, depositions/transcripts, and other materials provided to me by Counsel, or requested by me from Counsel. Upon retrieval, receipt, and review I considered documents for possible inclusion in the evaluation for this

report. If additional relevant proprietary documentation was required, and I was unable to independently locate this data/information, I made a request of Counsel for any related documents to be reviewed by me. I analyzed these documents for their regulatory relevance and conformity to industry practices and standards in forming my opinions in the same manner I would have assessed them when I was a premarket evaluator or the chief medical device compliance officer at FDA, and also in the same way I would evaluate them in my current capacity as a consultant to companies on medical device regulatory aspects.

The employed methods also include my reviews of depositions, corresponding exhibits, potentially associated with regulatory affairs, post-market surveillance, device design and manufacturing, and medical services, among others. These sources provide me with additional information about the company's action and understanding, which can inform my regulatory assessment.

Based upon my analysis of these documents and information, as well as my experience, knowledge, and training, I have formed opinions with regard to the Arizant/3M Bair Hugger Models 505, 750 and 775. Each of the opinions set forth below is held to a reasonable degree of scientific and regulatory certainty. My prior testimony is listed in Exhibit C. I have no publications in the past 10 years.

I may use visual aids or demonstrative exhibits, such as diagrams, images, slides or charts, to illustrate and or explain my opinions and analyses in this report, as well as excerpts, charts, and other information from the materials I have cited in my report or identified in the materials reviewed.

There are additional materials I expect to review in connection with my work in this case, and I reserve the right to supplement this report and my opinions after that review is completed and as discovery progresses in this litigation.

The name of the company involved in this litigation has changed over time. Originally the company was Augustine Medical, followed by Arizant, and now 3M. My opinions refer to company activities that span a period of time when the name of the company changed. Therefore, for example, I may refer to 3M/Arizant or Augustine Medical/Arizant.

1. It is my opinion that safety and effectiveness factored into FDA's review of every Bair Hugger 510(k).

The undated expert report for Plaintiff by Dr. Yadin David discusses premarket notifications [510(k)s] as well as safety and effectiveness.[34] The 510(k) process is a legitimate premarket process wherein FDA must consider safety and effectiveness aspects identified in statute and regulation to determine whether a new device is substantially equivalent to a legally marketed predicate. FDA did so for every 510(k) for Bair Hugger devices.

In the above background of my report I provide details on FDA's device classification system and the purpose of a 510(k). A 510(k) is used as a basis for FDA to determine whether a new device is substantially equivalent to a legally marketed device. FDA can also bring to bear other information it deems necessary to evaluate a 510(k) in addition to what is submitted in a 510(k).[35] Data submitted in a 510(k) must demonstrate that the new device is "as safe and effective as a legally marketed device."[36]

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[34] Hazard Analysis Report: Bair Hugger Patient Warming System, Yadin David, Ed.D., P.E., C.C.E.

[35] See for example, "FDA relies upon information provided about the predicate device, in addition to the information in our files as appropriate..." in FDA guidance, https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf.

[36] 515(i) of the FDCA.

The 510(k) standard is a comparative standard of safety and effectiveness, i.e., comparison of the new device to a legally marketed predicate that is not Class III. The standard for a premarket approval device is an independent determination of safety and effectiveness.[37]

The methodology used by FDA to determine whether any device is substantially equivalent is further described in statute, regulation and guidance.[38] There are several decisions FDA must make when determining substantial equivalence in every 510(k). Three decisions pertain to the intended use of the device, its technology, and performance data.

The new device must have the same intended use as the predicate for the new device to be found equivalent. As noted in FDA guidance FDA must consider issues of safety and effectiveness when comparing any differences in indications for use and claims. When comparing technology FDA makes it clear in guidance that it must consider the effect of differences of technology on safety and effectiveness. When evaluating the submitted performance data, e.g., electrical and mechanical safety, FDA must consider if the data demonstrate equivalent safety and effectiveness.

Additional evidence supports the fact that FDA considers safety and effectiveness factors when evaluating every 510(k). That evidence includes, for example, (1) an FDA Working Group's opinions on 510(k)s (2) the FDA definition of "valid scientific evidence" (3) the FDA definition of "safe" (4) statements in FDA guidance (5) the prohibition on equivalence to unsafe or ineffective devices, and (6) the FDA classification of the device type designated by regulation as "Thermal Regulating System".

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[37] Even though a PMA determination of safety and effectiveness is "independent" the clinical studies used to support safety and effectiveness are always on the basis of comparison to the standard of care, often including legally marketed Class II medical devices used as controls in studies.

[38] Evaluating Substantial Equivalence in Premarket Notifications, https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf, 515(i) of the FDCA and 21 CFR Part 807.

FDA Working Group Opinions

In August 2010, an FDA 510(k) Working Group carefully assessed the 510(k) program and provided recommendations to senior FDA management.[39] The report states the following in regard to safety and effectiveness determinations in 510(k)s (emphasis added):

> "With the exception of certain lower risk devices that are exempt from premarket review, CDRH reviews the safety and effectiveness of medical devices for their intended use prior to marketing. Under the premarket approval (PMA) process, each manufacturer must independently demonstrate reasonable assurance of the safety and effectiveness of its device for its intended use. Under the premarket notification (510(k)) process, CDRH will clear a new device if it finds, through review of a 510(k) submission, that the device is substantially equivalent to a predicate. Generally, predicate devices, as largely class II devices, are those for which there is a reasonable assurance of safety and effectiveness with general and applicable special controls."

> "The 510(k) program, as it currently exists,[40] is intended to support FDA's public health mission by meeting two important goals: making available to consumers devices that are safe and effective, and fostering innovation in the medical device industry."

> "When a predicate has a well established risk/benefit profile and is generally well regarded by the healthcare community, a premarket comparison of a new device

[39] CDRH Internal Preliminary Evaluations – Volume 1, 510(k) Working Group, Preliminary Report and Recommendations, http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsand Tobacco/CDRH/CDRHReports/UCM220784.pdf.

[40] The report describes the 510(k) process prior to the assessment by the FDA committee and includes the time when the Bair Hugger device was first evaluated by FDA.

> to that predicate, with sufficient information, can provide reasonable assurance that the device, subject to general and applicable special controls, is safe and effective for its intended use."

In an FDA draft guidance entitled "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics" FDA provides ample evidence of its evaluation in a 510(k) of the safety and effectiveness of a device.[41] The guidance states (emphasis added):

> The standard for a determination of substantial equivalence in a 510(k) review is set out in section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)).
>
> Substantial Equivalence
>
> (i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—(i) has the same technological characteristics as the predicate device, or (ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device. . .

[41] Benefit-Risk Factors to Consider When Determining substantial Equivalence, http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm282958.htm.

"Different technological characteristics" is defined in section 513(i)(1)(B) of the FD&C Act (21 U.S.C. § 360c(i)(1)(B)) as: with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device. . .

...if FDA determines that the different technological characteristics do not raise different questions of safety and effectiveness, FDA will then evaluate the technological differences between the new device and the predicate devices to determine their effect on safety and effectiveness. . .

FDA determines the "safety and effectiveness of a device" by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," among other relevant factors. . .

When FDA is reviewing a new device that has different technological characteristics than the predicate device, performance data may be necessary to assess the safety and effectiveness of the new device as compared to the predicate device. When evaluating the performance data, FDA may consider the risks and benefits of the new device in comparison to the predicate device before making a substantial equivalence determination. The type and quantity of performance data that may be necessary to support a determination of substantial equivalence depends upon the new device. Performance data may be generated from both non-clinical and clinical testing, and both non-clinical and clinical data can play a role in FDA's evaluation of benefits and risks. Both types of performance data can provide information relating to the benefit and risk factors discussed in this guidance.

The FDA standard of "Valid Scientific Evidence" applies to both PMAs and the 510(k) Device Classification Process

The determination of safety and effectiveness in a PMA and a finding of substantial equivalence in a 510(k) is based on the statutory and regulatory standard of valid scientific evidence, as stated in regulations as follows:[42]

> "(1) Although the manufacturer may submit any form of evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.
>
> (2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly

[42] 21 CFR §860.7(c)(1). This provision is also referenced in the FDA guidance concerning benefit-risk, https://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm282958.htm .

> and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use."

The 510(k) for the Model 750 included a bibliography of published studies related to burns and the risk of airborne contamination.[43] These papers constitute valid scientific evidence by the regulatory standard noted above.

There is only one definition of "Safe" that applies to all medical devices.

FDA regulations for medical devices contain only one definition of "safe" that applies to all devices. It states as follows:[44]

> There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

FDA Guidance confirms safety and effectiveness are factors considered in a 510(k).

[43] 3MBH00047033.

[44] 21 CFR §860.7(d)(1).

I refer above to the statutory and regulatory provisions regarding substantial equivalence. There are other examples confirming FDA's evaluation of safety and effectiveness in a 510(k). The Act has been amended several times.[45] One such change was the Medical Device User Fee Act of 2002 (MDUFMA).[46] According to FDA, MDUFMA was enacted "in order to provide the Food and Drug Administration (FDA) with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier time…"[47]

A guidance issued by FDA on the determination of substantial equivalence notes the following (emphasis added):[48]

> "Because devices are classified according to the level of regulatory control necessary to provide a reasonable assurance of safety and effectiveness, classification of a new device through the 510(k) process requires FDA to determine the issues of safety and effectiveness presented by the new device, and the regulatory controls necessary to address those issues."
>
> ***
>
> "The 510(k) review standard (substantial equivalence of a new device to a legally marketed (predicate device) differs from the PMA review standard (reasonable assurance of safety and effectiveness). The 510(k) review standard is comparative whereas the PMA standard relies on an independent demonstration of safety and effectiveness.

[45] Amendments to the Federal Food, Drug and Cosmetic Act, http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/default.htm.

[46] PL 107-250 (Oct. 26, 2002).

[47] MDUFA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109149.htm.

[48] Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf.

Nonetheless, the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review."

FDA cannot find a device to be substantially equivalent to an unsafe or ineffective predicate.

FDA has statutory and administrative tools at its disposal that it uses to eliminate unsafe or ineffective devices from consideration as predicates in a new 510(k). The Act provides, "A device may not be found to be substantially equivalent to a predicate device that has been removed from the market by FDA or that has been determined to be misbranded or adulterated by a judicial order."[49] The Act also provides a mechanism for removing Banned Devices from the market and excluding them as predicates.[50]

FDA may find devices adulterated and/or misbranded as a result of facility inspections or enforcement actions.[51] FDA may ban a device.[52] Recalled devices may be misbranded or adulterated.[53] In the case of devices related to violative facility inspections FDA has broad authority to exercise enforcement discretion when determining whether devices manufactured in the facility may continue to be claimed as predicates.

Thus, there are several means at FDA's disposal to eliminate unsafe or ineffective devices as potential candidates to be used in establishing substantial equivalence. None of the Arizant devices claimed as predicates in Arizant 510(k)s have been determined by FDA to be

[49] 21 USC §360c(i)(2) and 21 CFR §807.100(b)(3).

[50] 21 USC §360f.

[51] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm.

[52] 21 CFR §895.101.

[53] 21 CFR §7.3(g).

unsafe or ineffective. FDA had no basis for action and took none against any of the devices Arizant claimed as predicates in their 510(k)s.

The FDA Cardiovascular Device Classification Panel reviewed data concerning the risks and benefits of existing thermal regulating devices and recommended the group to be Class II.

Expert panels, composed of external clinical and scientific expert consultants, established by FDA classified all devices on the market in 1976 (and those found substantially equivalent to those devices). Those classification panels have transitioned to become the current advisory committees chartered by FDA. These panels rendered safety and effectiveness evaluations of the devices under consideration, creating the initial clinical and scientific basis for future equivalent devices. As regulations provide (emphasis added):[54]

> In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:
> (1) Considers the factors set forth in 860.7 relating to the determination of safety and effectiveness;
> (2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in 860.7;
> (3) Answers the questions in the classification questionnaire applicable to the device being classified;
> (4) Completes a supplemental data sheet for the device;
> (5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter.
> (d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of each class in 860.3(c), the panel submits to the Commissioner a recommendation regarding the classification of the device.

FDA reviewed the recommendations of the Cardiovascular Classification Panel and published the final classification regulations on February 5, 1980.[55] The regulations codified the

[54] 21 CFR §860.84(c).

[55] 46 FR 7907-7971, Feb. 5, 1980.

classification of "thermal regulating systems" under 21 CFR §870.5900 into Class II. There are currently no special controls for this type of device. The Class II classifications applied to submissions for subsequent thermal regulating systems, such as the Bair Hugger Models 500 and 750, making them eligible for the 510(k) premarket pathway.

Summation

It is my opinion, based on the above evidence, that safety and effectiveness factors in to the evaluation of equivalence in every 510(k). This was the case for every Bair Hugger 510(k) FDA evaluated.

2. It is my opinion that the Traditional 510(k)s for the Bair Hugger Models 505 and 750 met all FDA premarket requirements, recommendations of guidance, and industry standards. FDA's orders clearing these devices provided, in part, reasonable assurance that the Bair Huggers were safe and effective.

Dr. Yadin's report contains a section entitled "The Bair Hugger's Troubling Regulatory History." Three of the four parts of this section concern the 510(k) process for the Bair Hugger devices. I find there is nothing troubling whatsoever about FDA's clearance of the Bair Hugger devices. As I will explain, contrary to Dr. David's assertion, the 510(k)s for the Models 505 and 750, the principle focus of Dr. David, were submitted in proper form and content, then evaluated and cleared by FDA according to standard FDA policy and procedure.

There is reasonable assurance that a Class II device is safe and effective when it meets all the general controls and any special controls.[56] One general control is the clearance by FDA of a 510(k) for a new device when that submission is required.

[56] 21 USC §360c.

Augustine Medical Inc. submitted a 510(k) to FDA dated April 5, 2000, for the Bair Hugger Model 750 Total Temperature Management System (K001149).[57] I evaluated this 510(k) as I would have during my long tenure as an expert reviewer for FDA and find that the 510(k) conforms to the FDA regulation concerning 510(k) submissions, 21 CFR Part 807 as I explain below.

The administrative and technical data and information addressing the submission requirements are identified in the Model 750 510(k) Table of Contents as follows:[58]

[57] 3MBH00046986-00047093.

[58] 3MBH00046994.

Table of Contents

Confidential Under Protective Order

The submission content and format follow FDA guidance and industry standards.[59] The 510(k) includes all necessary administrative information, technical descriptive information for the Model 750, and technical comparison of the Model 750 to the legally marketed Model 505 Total Temperature Management system (K960167) used by Augustine Medical as the legally marketed predicate for comparative purposes. I find, based on my review and analysis of the original submission and supplemental information submitted to FDA by Augustine Medical, that the submission contains ample and sufficient test data in Section E base on FDA guidance at that point in time. Labeling in Appendix A meets the requirements of the FDA prescription device labeling regulation, 21 CFR §801.109 in that it contains all the required elements identified in the labeling regulation and it is comparable to the predicate labeling.

As I note above in this report, comparable intended use and technology are two essential decision criteria that must be satisfied for a new device to be found substantially equivalent to a legally marketed predicate. There are sufficient data and information in the original submission and the supplemental data submitted to FDA for me to assess and conclude that the Model 750 has the same intended use as the predicate and that the technological characteristics of the Model 750, although not identical to the predicate, do not raise new types of safety and effectiveness issues.

The Bair Hugger system as described in the submission consists of the portable forced air warming unit, a Bair Hugger blanket, and Model 241 fluid warming system if fluid warming is

[59] FDA 510(k) guidance, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

desired.[60] I note previously in this report the prior 510(k)s for the Bair Hugger blankets and fluid warmer.[61]

Augustine Medical Inc. reported to FDA in the 510(k) that it relied on voluntary domestic and international test and design standards, and FDA guidance including the following:

EN 60601-1	Electrical safety
EN 60602-2	EMC
ISO 9000	Quality Management
EN 5501	EMC

A Software Requirements Specification (SRS) is documented and approved.

Standards and documents used as references include:

- FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (1998),
- EN 60601-1-4 Medical Electrical Equipment Part 1: General Requirements for Safety Section 1.4 Collateral Standard: General Requirements for Programmable Electrical Medical Systems
- FDA's Guidance for the General Principles of Software Validation – Draft Guidance (1997)
- IEEE Standard 1012-1986; IEEE Standard for Software Verification and Validation Plans
- IEEE Standard 1016-1987; IEEE Standard Practice for Software Design Descriptions

Augustine Medical Inc. amended the 510(k) by letter dated June 1, 2000, to notify FDA it was not marketing the Model 750 with a HEPA filter.[62] Deposition testimony I will discuss later in this report indicates that the Model 750 was not marketed with the HEPA filter but with a filter similar to the predicate. This change did not impede a finding of substantial equivalence since the predicate did not have a HEPA filter.

As noted earlier in this report, FDA requested additional information from Augustine Medical Inc. on July 6, 2000, and Augustine Medical responded to the request. FDA cleared the

[60] 3MBH00047000.

[61] 3MBH00047012.

[62] 3MBH00046971.

Model 750 as a prescription device on September 6, 2000.[63] After clearance, Augustine Medical Inc. informed FDA of modifications to the Model 750 but FDA determined that a new 510(k) was not needed.[64]

I examined the 510(k) litigation production for the Model 505 (K960167), the predicate for the Model 750.[65] This 510(k), like the one for the Model 750, included all the necessary administrative information, substantial technical test data, and adequate labeling according to FDA regulation. The data and information established that the Model 505 had the same intended use as the predicate, there were no new issues of safety and effectiveness, and the data supported the decision that the Model 505 was substantially equivalent.

Both clearance orders from FDA for the Models 505 and 750 provided, in part, reasonable assurance of their safety and effectiveness according to statute.[66] There is nothing troubling in the 510(k) submission records.

3. It is my opinion that after clearance of the Model 750 FDA reconfirmed the safety and effectiveness of the Bair Hugger forced air technology by clearing additional 510(k)s for additional uses and new promotional claims.

As with the FDA clearances for the Models 505 and 750, there is nothing troubling about the other clearances for Bair Hugger modifications and accessories. After FDA cleared the 510(k) for the Model 750 on September 6, 2000, Augustine Medical, then later becoming Arizant Healthcare Inc., submitted additional 510(k)s to FDA for the Bair Hugger. Each time FDA evaluated and cleared a new Arizant Bair Hugger 510(k), the FDA evaluators by policy

[63] 3MBH00046940-00046941.

[64] 3MBH00046932.

[65] 3MBH00047137-00047384.

[66] For example: 3MBH00047159-00047173, 3MBH00047213-00047255.

relied on prior submissions, and other information they can bring to bear according to FDA policy and procedure, such as knowledge of the predicates and their post market performance. FDA was reconfirming the safety and effectiveness of the Bair Hugger technology based on current information with every clearance.

There were several such 510(k)s submitted by Augustine Medical and Arizant after clearance of the Model 750. Augustine Medical submitted a 510(k) (K021473) for modifications to the Models 200, 500 and 700 units with blankets to add the Model 459 patient cooling set.[67] Then FDA evaluated and cleared a Special 510(k) (K041686) to add additional benefit data for the technology.[68] Finally, FDA evaluated and cleared a Special 510(k) (K053645) to add a reduction of anxiety claim based on published data.[69] In all cases the intended use of the devices, except for the cooling function of the Model 459, was localized temperature therapy.

4. It is my opinion that FDA cleared the Model 750 with full knowledge that the air filter to be used in the Model 750 was not a HEPA filter. There is no FDA regulatory requirement for a warming device to meet a specific air filter standard.

On page 20 Dr. David begins a discussion on the filter used in the Model 750. He states that the Model 750 was introduced in 2003. FDA cleared the Model 750 on September 9, 2000. Dr. David asserts "...the Defendant made an unpublished filter change..." for the Model 750 "and never notified the FDA or its customers of this change." He references correspondence dated June 1, 2000 from Augustine Medical to the FDA reviewer of the 510(k) for the Model

[67] http://www.accessdata.fda.gov/cdrh_docs/pdf2/K021473.pdf.

[68] 3MBH00047618-00047723.

[69] 3MBH00047731-00047854.

750. The FDA reviewer was informed of the change in the filter from a HEPA filter to one that Augustine Medical described in the June letter as follows.[70]

> We want to amend the 510(k) to include a filter that is substantially equivalent to the filter currently being used in all of our cleared devices. The description of this filter will be the same, but the physical size will be slightly smaller. With this amendment, the filters in our currently cleared devices (including the SE device Model 505) and the Model 750 will all be 0.2 micron filters.

The revised comparative table attached to the June 2000 letter to FDA describes the filter for the Model 750 as either "0.2 µM or HEPA." The Model 505 filter in the comparative table is described as 0.2 µM. The table also compares such features as Heat generated and Airflow. The revised Summary of Safety and Effectiveness states that "...air is filtered through a filter" instead of "through a HEPA filter." The attached revised Specifications for the Model 750 lists the Filtration System as "0.2 µM or HEPA level (optional)."[71]

It is clear that FDA was informed in the June letter that the Model 750 would include, as an option, a 0.2µm filter as did the Model 505. The publicly available Summary of Safety and Effectiveness lists the correct information regarding the filter. The revised Specifications for the Model 750 include the correct optional filter characteristics. Contrary to Dr. David's assertion, Augustine Medical did not state in the letter that the Model 750 filter had the same efficiency as the filter in the Model 505.

Dr. David discusses the differences in filter media between the Model 505 and Model 750. The filters in each model were both 0.2µm filters but the filter media in each model had different efficiencies at the same 0.3µm level and air flow.[72] This difference is evidently the

[70] 3MBH00049671-00049672.

[71] 3MBH00046975-00046978.

[72] Hansen deposition, 11/2/16, Exhibit 6.

"unpublished information" to which Dr. David refers. He also implies that the findings in the Hall and Zink publications were not applicable to the Model 750.

Augustine Medical stated to FDA that the filters used in both models were "substantially equivalent" 0.2 micron filters. In other words the Model 505 filter media (M10) used until 2009 was substantially equivalent to the Model 750 filter media (M20). Substantial equivalence is a finding by FDA concerning a new finished device and not a component but FDA must consider technological changes in deciding if a new device is substantially equivalent.

FDA guidance on technological changes provides FDA's thinking on this topic. FDA stated in a 1986 Blue Book guidance that it finds devices with technological features to be not equivalent when the new feature (emphasis added) "...could adversely affect safety or effectiveness in a way that is consequential under the conditions of intended use."[73] FDA guidance on benefit-risk factors to consider associated with technological change when evaluating 510(k)s must also be considered.[74]

It is my opinion that Augustine Medical's change in filter media from M10 to M20 is not "consequential under the conditions of use." As a result, even recognizing that the media is different the Model 505 and 750 are substantially equivalent. I have four bases for my opinion as follows: (1) There are no publications prior to or after the Model 750 was cleared by FDA that have verified an infection related to any Bair Hugger regardless of filter media. (2) There are no FDA Class II device filter Special Controls for thermal regulating systems, no voluntary standards that stipulate specifications for filters used on thermal regulating systems, nor any

[73] FDA Guidance, K86-3.

[74] FDA Guidance, Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics, https://www.fda.gov/RegulatoryInformation/Guidances/ucm282958.htm.

required hospital device filter standards the Bair Hugger must meet.[75] Therefore, there is flexibility in the filter media specifications that can apply to the Bair Hugger filter. (3) The 2016/2017 3M Risk Managements Report for the Bair Hugger, retroactive to the Models 505 and 750, indicates the surgical site risk of infection and assigns the lowest risk level of R1 to the risk.[76] (4) The M10 and M20 filter media have met at least the same Minimum Efficiency reporting Value (MERV) 14 rating that is acceptable for surgery.[77]

Mr. VanDuren testified:[78]

> Well MERV 14 is the -- is -- is in a class of air filters that are specified by ASHRAE as being bacterial exclusion filters and are acceptable for use in healthcare facilities.

***

Mr. Crowder from Pentair (acquired Porous Media) testified as follows:[79]

> **A. Correct.**
> Q. Okay. And have you seen test data establishing a particular MERV rating for that M20 media in the specific filters that Porous/Pentair makes for 3M?
> **A. Yes.**

[75] There are filter standards for operating room air filtration but not for devices in operating rooms.

[76] R1 is described in the 2016/2017 RMR as "Risk is minimum. The potential hazards have either been eliminated or adequately mitigated considering the current state of the art and is supported by an appropriate risk/benefit analysis."

[77] VanDuren depo, Page 22:4-10. See also ANSI/ASHRAE 52.2, https://www.ashrae.org/..

[78] Id. Page 105:9-12.

[79] Crowder deposition, 3/16/17, Page 91:21-92:6 and 54:4-6.

Q. And what MERV rating is that?
A. Fourteen.
Q. Would it be fair to say that a MERV 14 filter is highly efficient at filtering small particles?
A. Yes.

***

A. My understanding is that both of the filter medias or -- that we have supplied would be capable of removing bacteria.

***

Mr. Hansen testified regarding standards as follows:[80]

Then you go on to state "...there is no standard requirement for the convective air warming devices." Do you see that?
A. Yes.
Q. So nobody had a standard out there. The FDA, CDC, National Institutes of Health, no one had a standard; is that right?
A. That's correct.

Next, to assess the benefit/risk of a technological change it is evident that the Model 750 incorporated improvements in design and performance compared to the Model 505 as follows:[81]

[80] Hansen deposition, 11/2/16, Page 169:17-24.

[81] 3MBH00047008.

Summary of Differences

- The Model 750 unit incorporates software as part of the primary temperature control system.
- The Model 750 unit provides greater airflow.
- The Model 750 unit measures the temperature at the distal end of the warming unit hose and displays it on the control panel; the Model 505 unit calculates this temperature. Because of this, the Model 750 unit uses a different warming unit hose.
- The Model 750 control panel includes independent switches for *Standby* mode and each temperature setting; the Model 505 control panel has one temperature select switch which, when pressed, changes the temperature setting to the next setting in the sequence.
- The Model 750 control panel includes an LCD window that displays error codes; because it lacks software, the Model 505 unit does not have an error code feature.
- The primary over temperature sensor for the Model 750 unit is set to 47 ± 2°C and the secondary over temperature sensor is set to 53 ± 3°C. The primary sensor for the Model 505 unit is set to 53 ± 3°C.
- The Model 750 unit can include a collapsible or non-collapsible warming unit hose with a variety of storage options.

These improvements, i.e., benefits, should be weighed against any potential increased risks posed by the device with use of the M20 media. FDA risk-benefit guidance states the following:

> *Increased Risk/Increased Benefit*: If the risks associated with the new device increase as compared to the predicate device, FDA may still determine that the new device is SE to the predicate device if, for example, FDA finds from a review of the new device's performance data that there are also increased benefits with the new device as compared to the predicate device.

Therefore, arguendo, although the M20 filter media is less efficient than the M10 media at a 0.3µm particle size (but equally efficient at larger relevant particle sizes according to Hansen), there were increased benefits of the Model 750 compared to the Model 505. As a result, it is my opinion that the Model 750 with the technological change in filter media had an acceptable benefit/risk ratio and was again substantially equivalent.

The argument that the Zink and Hall publication and poster are not applicable to the Model 750 due to the change in media and airflow is incorrect. Although the filter media in the Series 500 devices in Zink publication and maybe the Hall poster was different from the Model 750 the publications demonstrated the fundamental utility of air filtration.[82] This is valid scientific evidence that can be applied to the Model 750. In any case, 3M/Arizant was not required to notify FDA of the change in media.

Dr. David's assertion that the use of the M20 media is "unpublished" implies that the filter media should be listed in labeling for the Model 750 and that FDA should have been told about the change in filter media. The fact of the matter is that FDA found the Model 750 to be substantially equivalent with labeling indicating only the 0.2µm filter characteristic. The original 510(k) did not list the efficiency specifications for the filter media and FDA did not ask for media specifications. Hansen testified regarding notification of customers regarding the change in media as follows:[83]

Q. That's why you didn't want to tell the customers about the nominal; isn't that right?
A. I thought it was misleading.
Q. Because 50 percent of the time they might not catch it and 50 percent of the time they might.
A. No. It was misleading because it wasn't relevant to the much larger particle sizes that are typical for fomites. These types of filters are much more efficient for larger filter sizes -- or excuse me -- larger particle sizes.

In sum, FDA cleared the Model 750 510(k) well aware that the filter was 0.2µm and not a HEPA filter like the predicate. FDA indicated that a HEPA filter could be optional. The filter met a MERV standard that applies to hospital filtration. There is no special control

[82] The Hall poster publication does not actually identify the model of Bair Hugger used in the test so there can be no confirmation of the media.

[83] Hansen deposition, 11/2/16, Page 110:6-15.

requirement for a warming device pertaining to filter specifications. FDA's clearance of the Model 750 established that it was substantially equivalent and therefore reasonably safe and effective for its intended use.

5. It is my opinion that the design history files for the Bair Hugger Models 505 and 750 provide reasonable assurance of the safety and effectiveness of the designs of these devices.

The FDA Quality System (QS) regulation sets forth the current good manufacturing (CGMP) requirements for medical devices.[84] The QS regulation governs the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. According to the QS regulation the requirements are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.

Manufacturers are required by the QS regulation to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.[85] Design control requirements include provisions for design and development planning, design inputs, design outputs, design reviews, design verification and validation, design transfer to manufacturing, and design changes. According to the QS regulation, the Design History File (DHF) shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.[86] These requirements became effective in 1997 but FDA afforded the industry a grace period for many months afterwards to enable the industry to implement the new requirements. For this

[84] 21 CFR Part 820.

[85] 21 CFR §820.30(a)(1).

[86] 21 CFR §820.30(j).

reason devices designed during this grace period and before may not have records addressing all aspects of the current QS regulation.

I examined the DHFs for the Models 505 and 750 as I did numerous times as chief compliance officer for medical devices at FDA. I relied on the QS regulation, FDA policies and practices, and FDA guidance in my review. I summarize below the contents of DHF for the Model 505, the original design DHF of the Bair Hugger Model 750, and a re-design of the Model 750 DHF.

Table 3 provides a brief summary of the required elements of a DHF and significant examples of the corresponding contents of the Bair Hugger DHFs. Based on my review I found the DHFs contain substantial evidence of the required elements for a compliant DHF.

Summary of Bair Hugger Models 505 and 750 Design History Files

	Model 750	Model 505
	BATES FORMAT 3MBH000XXXXX	BATES FORMAT 3MBH00XXXXXX
DHF Bates	46310-00046818 346819-00046820 46186-46309	127752-129010
FDA DHF Requirements (21 CFR §820.30)	Corresponding DHF Data	
Design and development plans	46729-46730, 46822-46903, 46829, 46200	127758-127796, 127814-127825
Design Input	46312-46313, 46405-46406, 46727, 46188	127754-127755
Design Output	46366, 46416-46439, 46532, 46534, 46562-46573, 46575-46587, 4678-46801	127756-127757, 127987-128131
Design Review	46356-46363, 46381, 46386, 46400, 46440-46441, 46491, 46526, 46547, 46557, 46574, 46598, 46666	12797-27800, 12807-12847
Design Verification	46391, 46404, 46496-46497, 46507-46508,46622 FASCO brochure, 46734, 46282	128132-128365

Design Validation	46668 beta testing, 46306-46307	127848, 12871-12872, 127938-127939
Design Transfer	46668 final design review production run	128745-128859

When reviewing the entire content of the DHFs, as I would as the chief compliance officer at FDA, I found the DHFs not only sufficiently complete but also the following aspects particularly noteworthy:

1. The design inputs are detailed for both the "reduced size" device (aka Model 505) and the "Cobra" file, i.e., the Model 750 Bair Hugger device file.

2. There is ample documentation of design verifications in the DHFs. The DHF information is the source of the information submitted to FDA in the 510(k). The verifications confirm that the design outputs met the requirements of the design inputs.

3. There are numerous required design meetings with various Augustine Medical Inc. staff to evaluate tests and to discuss progress towards completion of the design process and transfer to manufacturing as required. I provide in the above table only a few examples of those meetings.

4. There is risk assessment information, including design and process FMEA, for the 750 redesign, to assess hazards and mitigation of the hazards. There is no record of an FMEA in the Model 505 DHF but this was not essential in a DHF at that point in time.

5. There is responsive information to the design validation requirements of the QS regulation.[87] Notably, there are beta sites consisting of hospitals where the devices were

[87] The QS regulation was published in 1997 but FDA allowed a grace period for industry implementation of design controls including a design history file.

evaluated by medical staff in operating rooms. Ample publications support the performance of the Models 505 and 750.[88]

6. The design inputs for the Model 750 include a requirement for an intake filter (prefilter) that is easy to change and with easy method for cleaning. The Model 505 DHF lists the 0.2µm filter as a design input. Additional records are in the file from the filter supplier.

7. It is remarkable that four years before FDA required design history files and compliance with other aspects of design control Augustine Medical was voluntarily implementing design controls.

In sum, the DHFs contained the data and information on the design process for the Models 505 and 750 that was required after the implementation of design controls in the Quality System regulation.

6. It is my opinion there was no unacceptable risk or regulatory imperative prompting Arizant to modify the Model 750 to include a filter at the distal end of the air supply hose or a silver coating to the interior of the hose.

On page 31 Dr. David begins a section entitled "Defendant's Refusal to Mitigate Patient Risk." He discusses "Project Ducky" and the evaluation of a silver coating on the interior of the hose. There are Bair Hugger design activities described in litigation records and discussed in depositions. Two of them are an activity to consider adding a filter at the distal end of the air supply hose where the blankets connect. The proximal end of the hose is connected to the heater/blower. The other design activity was to consider coating the interior of the air supply hose with an antimicrobial.

[88] Papers in production from 1969 to 2015 regarding normothermia and assessment of infection risks.

The litigation records describe the activity to add the filter as "Project Ducky." Based on deposition testimony this activity was undertaken by Arizant as a response to what industry calls the "Voice of the Customer" design input, rather than a response to an unacceptable risk that required mitigation, such as confirmed surgical site infections caused by the Bair Hugger.

Karl Zgoda, Senior Manager of Product Development at Arizant, described the purpose of the project as follows:[89]

> **A.** I would say that's not correct. It was a project to investigate potential filtration solutions to issue -- to concerns customers may express over filtration. But I would not say it was a goal to add HEPA filter --

Gary Maharaj, CEO of Arizant, also testified regarding the motivation for the additional filter as follows:[90]

> **It was a feasibility assessment, as I recall, to understand because of some customer perceptions about wanting to have an end-of-hose filtration, and so we undertook it to see if we could accomplish that while maintaining the effectiveness of the therapy.**

The other design activity was to assess the addition of a silver coating to the interior of the hose. It is my experience evaluating silver coatings on devices that the coating acts on the surface only. Silver coatings also act only in the presence of moisture, therefore, it would not be effective on moisture-free bacteria in an air flow media. Mr. Hansen testified as follows:[91]

[89] Karl Zgoda deposition, 2/24/17, Page 86:8-12.

[90] Gary Maharaj deposition, 1/18/17, Page 197:11-16.

[91] Hansen deposition, 11/2/16, Page 265:2-18.

Q. With regard to the hose and the use of antimicrobial material, was that implemented or not?

A. No, it was not.

Q. What were the reasons it was not implemented?

A. We believed that the material was unlikely to be effective.

Q. What was that decision based on?

A. The method of operation for the material required moisture, as I recall, and the hose is a dry environment.

Q. You're saying the application of the antimicrobial material required water?

A. To my understanding, yes.

Q. When it was applied?

A. Well if it's going to release its active ingredient, it needed some moisture to do so.

Arizant's microbiologist stated the following:[92]

I think that it is possible to coat all your suggested surfaces below with the quat antimicrobials and other chemistries. However, I think that realistically speaking you would need reasonable residence time (at least 15 minutes) and humid air to do a decent job of bacterial kill. It may be that you really make a

The testimony provides evidence that Arizant diligently assessed the end-hose filter as a response to customer perceptions, which can be a valid design input. There is no testimony that Arizant's consideration of adding a filter at the distal end of the hose was initiated as a mitigation to an unacceptable risk or a nonconformity requiring a corrective and preventive action as required by regulation.

Arizant determined through testing that the end hose filter had an impact on effective air flow, thus reducing the benefit of the device.[93] Likewise, the company diligently investigated a coating to the interior of the hose but determined the change to be ineffective due to the

[92] 3MBH00542396.

[93] Example, Hansen deposition, Page 282:3-284:6.

properties of silver coatings and the requirements for moisture for effectiveness. Also, Mr. Zgoda testified as follows that the potential supplier of the silver coating could not ramp up to produce the coating as requested:[94]

> "They were a company that had the technology to apply antimicrobial coatings to products, but they didn't really have the ability to -- to do it in production for companies. It was more of a, what I would call a technology or proof-of-concept idea at the time."

Thus, it is my opinion that the company was reasonable and prudent in considering the two design changes and evaluating them according to industry standards. The changes were not adopted for valid scientific reasons. There was no regulatory requirement to pursue these changes or to report these design activities to FDA.

7. It is my opinion the MedWatch reports to FDA in 2016 from Dr. Augustine and his company, all of which were third hand voluntary reports based on Dr. Augustine aided litigation, are biased, incomplete, and unverified. 3M has a reasonable regulatory basis for not reporting litigation-based events to FDA concerning allegations of infections associated with a Bair Hugger.

The Complaint in Paragraph 74 alleges that 3M/Arizant failed to conduct surveillance of the Bair Hugger. One regulatory post market surveillance requirement concerns the submission of medical device reports.

Manufacturers are required by regulation to collect and investigate complaints and submit Medical Device Reports to FDA of reportable deaths, serious injuries and malfunctions. Manufacturers must create procedures, based on the regulations and industry standards and practices associated with those regulations.[95] FDA maintains a public record of MDRs in its

[94] Karl Zgoda, 2/24/17, Page 164:14-18.

[95] 21 CFR Part 803 and 21 §CFR 820.198.

Manufacturer and User Facility Device Experience (MAUDE) database.[96] Reported events in the MAUDE database are either mandatory reports from manufacturers, health care facilities, or importers, or are voluntary reports from health care professionals, consumers or patients.[97]

I searched the FDA MAUDE database for the period 2000 to 2016 for reports related to Bair Hugger devices. I also searched the database for the competing "Hot Dog" device marketed by Augustine Medical Management.[98] The results do not necessarily comprise all the MDRs submitted by these manufacturers if a report was not captured by my search terms.

There are MAUDE reports prior to 2016 for the Bair Hugger. I found 10 MAUDE reports for 2013. A 3M risk management report also notes 10 MAUDE reports.[99] For 2013 the 3M risk management report indicates 8 alleged injury complaints with 1 claim of infection. For 2014 I found 9 MAUDE reports as the 3M report also indicates. For the same period the 3M risk report indicates 29 complaints with 2 claims of infection. For 2015 there are 8 MAUDE reports, and one concerns an infection. The 3M report also indicates 8 MAUDE reports for 2015 and 113 complaints with 103 of those are claims of infection. In 2016 there are 500 MAUDE reports including reference to infections.

According to the following deposition testimony by Dr. Scott D. Augustine he and his company submitted to FDA around 600 MedWatch reports:[100]

> Q. So when you find out about a new lawsuit, somebody on -- in your employ uses you template and fills out an MDR and submits it to the FDA?
> A. Well, we wait 30 days first so that 3M has violated the law on that particular complaint and then we file. But we're way behind right now, so we're more than 30 days out.

[96] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/results.cfm.

[97] MedWatch, https://www.fda.gov/safety/medwatch/.

[98] Search dated 4/21/17.

[99] 3MBH02281401-02281452.

[100] Scott D. Augustine deposition, 3/31/17, Pages 204:22-205:16.

Q. Do you have a rough estimate as to how many you've filed at this point?
A. Probably around 600.
Q. And for any of those 600, have you asked permission of the -- the individual who is identified in the MedWatch MDR to submit an MDR about their situation?
A. No.
Q. In any of those 600 or so, have you communicated with either the hospital or the medical staff involved in the actual treatment of the -- of the patient to see if they were submitting an MDR?
A. No.

I find the delay by Dr. Augustine in reporting the events for a significant period of time after he had concluded that they should be reported so as to impugn the integrity of 3M to be unconscionable. A MedWatch report is intended as a vehicle for reporting serious problems with human medical products and should be timely reported, not delayed for competitive purposes.

The new lawsuits referred to above were catalyzed by activities that Dr. Augustine and his staff characterized as follows:[101]

Plaintiffs' lawyers are already trolling for Bair Hugger product liability cases. See http://www.stlouisinjurylawblog.com/35 and www.surgicalsiteinfectionattorneys.com.

***

Guide
David and Gabe,

Scott and I are preparing a detailed guide to suing 3M/Bair Hugger for orthopedic implant infections. It will contain background, summaries of and links to scientific articles, explanations of the etiology of

[101] Id. Exhibits 16 and 70.

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joint infections, a timeline of 3M's knowledge and failure to warn, discovery suggestions...and a half-dozen other useful things.

We intend to offer it to other plaintiffs' firms around the country who express an interest in jumping on this bandwagon. Our staff is preparing a list of the email addresses of AAJ members who do this work, and we may do an email blast. Communications in the AAJ publications may also be a good idea.

My question: Would you like KH to be the author of this Guide? It would help establish KH as the leader in this area. Of course, if KH is the listed author, you guys will want to be comfortable with the content, and I will run everything past you. We are going forward either way, but I want to give you the opportunity if you are interested.

Randy

Dr. Augustine and his company created a draft template for Bair Hugger MedWatch reports that they would populate with some information from the litigation complaints and then file with FDA.[102] I examined a sample of the 2016 Bair Hugger reports on FDA's web site in their native form and a downloaded excel spreadsheet of all the reports and they generally follow the form and content of the draft template.[103] All the reports repeat the same alleged Augustine theory of the connection of the Bair Hugger to surgical site infections.

Dr. Augustine testified he had previously written most of a MedWatch form submitted to FDA by a Dr. Gauthier.[104] The MedWatch form refers to a Baker and King article and to Dr. Suzanne Beavers. The portion of the Baker and King article in the MedWatch report does

[102] Id. Exhibits 32 and 33.

[103] See for example, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=6141608&pc=DWJ.

[104] Id. Exhibit 29 and Page 160:23-161:24.

not identify a Bair Hugger device and actually refers to another device. The MedWatch conclusions pertaining to Dr. Beavers are misstated.[105]

The FDA MAUDE web site discusses the purpose and interpretation of required and voluntary reporters.[106] FDA states on the MAUDE web site that the data in reports may be incomplete, inaccurate, untimely, unverified or biased as follows:

> Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important postmarket surveillance data sources.
>
> - Please note that the MAUDE web search feature is limited to adverse event reports within the past 10 years.
> - MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.
> - Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
> - MAUDE data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.
> - Variations in trade, product, and company names affect search results. Searches only retrieve records that contain the search term(s) provided by the requester.
> - Submission of a medical device report and the FDA's release of that information is not necessarily an admission that a product, user facility, importer, distributor, manufacturer, or medical personnel caused or contributed to the event.
> - Certain types of report information are protected from public disclosure under the Freedom of Information Act (FOIA). If a report contains trade secret or confidential business information, that text is replaced by "(b)(4)". If a report contains personnel or medical files information, that text is replaced by "(b)(6)". The designations "(b)(4)" and "(b)(6)" refer to the exemptions in the FOIA. For example, "(b)(4)" may be found in place of the product's composition and "(b)(6)" may be found in place of a patient's age.
> - MAUDE is updated monthly and the search page reflects the date of the most recent update. The FDA seeks to include all reports received prior to the update but the inclusion of some reports may be delayed.

The MedWatch reports submitted by Dr. Augustine and his company are third hand at best. They are not voluntarily reported to FDA by the patient or their doctor, nor are they reported to FDA by a law firm.

The MedWatch reports submitted by Dr. Augustine and his company to FDA are incomplete. Many sections of each of the submitted reports are blank or indicated in FDA's

[105] Id. Exhibit 31.

[106] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM.

MAUDE record as information was not reported to FDA. The alleged causation explanations provided by Dr. Augustine and his company in the MedWatch reports are incomplete root cause analyses and conjecture in that all potential causes of the alleged infections for each patient are not identified and reasons for discounting all of these potential causes except for the Bair Hugger independently for each patient are absent. The alleged causation in all cases is simply based on Dr. Augustine's standard alleged legal theory.

The Event Descriptions in the Dr. Augustine MAUDE reports contain some identifying information of the patient and his/her treatment, allegations of causation based on the Plaintiff's complaint, and litigation based assertions. I consider these Event Descriptions to contain, in part, unverified and biased data. The reports cannot be interpreted or used to reach conclusions about the association, severity, or frequency of problems in any patient.

I believe the alleged circumstances in each of Dr. Augustine's litigation based complaints have not been scientifically or medically verified making it difficult to establish, as FDA states, "the cause-and-effect relationship of each event" in any given patient. The complaints and MedWatch reports are biased because Dr. Augustine and his company catalyzed the complaints and submitted the MedWatch reports. Dr. Augustine is an industry competitor and antagonist to the marketing of forced air warming devices. His deposition testimony confirms he played a role in the pending litigation and formulation of the legal theory upon which the complaints and MedWatch reports were generated.

The Event Descriptions in the MedWatch reports submitted by Dr. Augustine include statements about 3M's failure to report MDRs for the events reported to FDA. The reports allege

Arizant/3M violated regulations due to lack of reporting of the events or timely reporting. Dr. Augustine testified as follows:[107]

> Well, 3M has a statutory obligation to do it. And once they've been notified by any legal document, and I assume a lawsuit is a legal document, the FDA statute says they've got 30 days to file. And since they haven't filed one of them, we're kind of doing their duty for them, you might say.

There are 20 MDRs for the Hot Dog device for the same time period I examined for the Bair Hugger. The reports for the Hot Dog describe device malfunctions and patient injuries. I believe that were it not for the litigation-based reports generated by Dr. Augustine the number of MAUDE reports for the Bair Hugger and the Hot Dog devices would be similar.

Suzanne M. Danielson, Director of Regulatory Affairs and Quality Compliance for 3M's Healthcare Business Group testified as follows concerning 3M's MDR reporting in general and specifically regarding the litigation based reports for the Bair Hugger:[108]

> We have a process for reviewing every complaint that comes into 3M, including a legal complaint, and that process involves assessing whether or not an injury occurred and then looking at -- we -- we apply the definition in the medical device regulation which states you review -- you review each event in terms of is there information that suggests that the event -- that the device may -- reasonably -- reasonable information to suggest that the device may have caused or contributed to the event.
>
> ***
>
> As I mentioned earlier, in this -- relative to complaints regarding infection, the only complaints that 3M has received has been through law firms related to litigation. So we have not received any facilities that have reported that they have a concern regarding infection in the Bair Hugger.
>
> ***
>
> In this case this is a -- we have a very unique situation here where there is many -- you

[107] Augustine deposition, 3/31/17, Page 205:21-206:2

[108] Suzanne M. Danielson deposition, 3/17/17, Pages 95:24-96:2, Page 100:4-9, Page 103:3-15, Page 119:10-22.

know, hundreds of legal cases that come in with essentially no information in terms of the specifics; so they talk about the Bair Hugger was used, the patient had infection. That's essentially the information that comes in. So each of those cases are reviewed, and the -- and in this context we have to -- we -- we have reviewed it in a very holistic way because the -- the complaints are questioning the design of the device. So we have reviewed it very holistically, we have utilized qualified persons, as defined, to evaluate the situation.

***

But I think in order to be completely responsive it would be important to share that the -- 3M has corresponded to the agency specifically relating to -- well over a year ago, relating to our MDR process, our MDR filing determinations so that the agency has a, I think a very good understanding of the situation, what's been reported, and the basis upon which we have made no-file decisions. And to that end, less than three -- two or three months ago the agency also inspected 3M's MDR files and complaint files and came to, at least at the close of the inspection, the conclusion that those files were adequate and the decisions were appropriate.

The 2016 FDA inspection to which Ms. Danielson refers in her testimony was a directed inspection of the 3M St. Paul and Eden Prairie facilities. A directed inspection is intended to investigate specific aspects of a facility as directed by the Center for Devices and Radiological Health (CDRH). It is clear that the direction of CDRH to the inspector was to investigate 3M MDR reporting practices related to the Bair Hugger. The 2016 inspection concluded with no significant observations identified by the inspector.

The Freedom of Information redacted FDA Establishment Inspection Report (EIR) for the 3M St. Paul facility states the following:

This inspectional assignment was requested due to CDRH receiving numerous MDRs citing litigation filed against 3M Corporation for contamination of surgical fields and subsequent patient infections from the Bair Hugger Patient Warming System (CDRH complaint #CPT1600206, dated 05/14/2015, and FDA consumer complaint #146481, dated 07/29/2016). In addition, this inspection was conducted as a follow-up to an outside complaint (FDA consumer complaint #147274, dated 09/28/2016) alleging waste heat contamination from the Bair Hugger Patient Warming System, lack of conformance to the firm's 510(k), and 3M Corporation's failure to file over 600 MDRs related to reports of patient infections. [redacted] (b) (4) As no manufacturing operations related to the Bair Hugger Patient Warming System occur at the St. Paul, MN facility, inspectional coverage at this facility included design controls, complaint handling, MDR reporting, corrective and preventive actions, and field actions with a focus on the Bair Hugger Patient Warming System. Details related to these elements are described in further detail within the sections below.

As part of this CDRH directed inspectional assignment, a comprehensive surveillance inspection was conducted at the 3M Eden Prairie, MN facility from 12/05-06/2016 with a focus on the Bair Hugger Patient Warming System. This facility is responsible for assembly operations, receipt of incoming components and subsequent inspection, finished device testing, servicing and

refurbishment of returned units, and corrective and preventive actions related to production issues. Complaint handling, regulatory reporting, and design controls are handled at the St. Paul, MN facility. Further details related to the 3M Eden Prairie, MN inspection can be found in its respective establishment inspection report.

***

On 12/08/2016, a closeout meeting was held with Dianne Gibbs, Infection Prevention Division Regulatory Affairs Director; Jon C. Platt, Infection Prevention Division Regulatory Affairs Manager; and [redacted] (b)(6) Regulatory Affairs Specialist. Suzanne M. Danielson, 3M Health Care Business Group Vice President of Regulatory Affairs & Quality Compliance, and Mike Besser, Infection Prevention Division Quality Manager, participated in the closeout meeting via teleconference. No FDA-483, Inspectional Observations, was issued as no significant observations were made. We discussed the one late MDR and the firm's current CAPA related to late MDR reporting. In addition, we discussed FDA inspectional timeframes and medical device registration activities.

FDA will release an EIR to manufacturer if no administrative or enforcement action is contemplated, or after enforcement action is concluded.[109]

[109] Release of EIR, https://www.fda.gov/downloads/aboutfda/transparency/publicdisclosure/glossaryofacronymsandabbreviations/ucm212061.pdf.

An EIR of a 2009-2010 inspection of Arizant covered the same regulatory issues as the 2016 inspection. I do not see any observations related to MDR violations in the inspection report. FDA noted the following in that EIR:[110]

> The firm has not initiated any CAPAs in response to contamination issues as no such issues have been brought to the firm's attention. A review of the complaint database from January 2006 – present did not reveal any issues with microbial air contamination as a result of using the patient warming units. It should be noted that Arizant uses a Cause Code "BG27 Contamination" (See Exhibit 4 for complaint code key) to indicate debris found within the blanket packaging. The explanation of the usage of this complaint code was provided by Dave Westlin. A query of complaints coded as BG27 did indicate it is used to code events involving foreign objects found within the blanket packaging. No microbial air contamination complaints were uncovered during the inspection. Multiple, independently-conducted studies were provided by the firm in response to the contamination inquiry. Collectively, the studies conclude the forced-air warming system does not increase bacterial contamination in the operating room. The provided studies include:

I discuss a 2010 Warning Letter from FDA later in this report but that letter concerned MDRs for complaints of burns. Reports for complaints relating to burns was resolved with FDA.

In 2015 3M communicated by letter to FDA regarding its complaint and MDR reporting practices concerning allegations of infection that were or may have been caused or contributed by Bair Huggers.[111] It is very evident to me that 3M was being proactive and transparent with FDA on the issue of allegations of infection and 3M's MDR reporting practices. As noted above the 2016 inspection was supportive of 3M's position on MDR reporting in that no observations were made by the inspector and FDA has issued no Warning Letter concerning this inspection.

Ms. Danielson's deposition refers to reporting of events that "reasonably suggest" a reportable event has occurred. The MDR regulation includes the following information on what constitutes information that "reasonably suggests" that a reportable event has occurred and who

[110] 3MBH00048072.

[111] December 14, 2015 correspondence, 3MBH02280982-02281003; November 29, 2016 correspondence, 3MBH02281065-02281067.

can determine that a device did not cause or contribute to a death or serious injury, or reportable malfunction as follows:[112]

> (c) *What kind of information reasonably suggests that a reportable event has occurred?*
>
> (1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
>
> (2) If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files (described in 803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.

3M did not submit MDRs to FDA for the Augustine-assisted litigation complaints of infection. In order to determine whether this was reasonable and in accordance with regulations I examined the information I describe above including: (1) the 3M/Arizant FDA inspection history, (2) 3M/Arizant's history of reporting events to FDA it concluded were reportable, (3) the testimony of 3M's corporate representative and Dr. Augustine, (4) 3M's transparent correspondence with FDA and (5) FDA regulations to assess 3M's decision not to report these complaints.

It is my opinion that 3M received, reviewed and evaluated all complaints it received, including the litigation-based complaints, as required by the Quality System regulation.[113] It is my opinion that 3M appropriately did not consider the litigation-based complaints to "reasonably suggest" that a Bair Hugger may have caused or contributed to an infection. As I note above, the litigation-based complaints and associated MedWatch reports submitted by Dr. Augustine are tainted by the biased, unverified and incomplete nature of those complaints and reports.

[112] 21 CFR §803.20(c).

[113] 21 CFR §820.198.

Importantly, the FDA inspections, one as recently as 2016, did not result in any observations by leading to advisories of violations. I found that 3M has a history of submitting MDRs for events other than the Augustine generated complaints and it is evident to me that 3M is well aware of its regulatory obligations and takes them seriously. As a result, I conclude that 3M's decision to not report the Augustine generated litigation-based complaints to FDA is compliant with the MDR regulation.

8. It is my opinion that the labeling for the Bair Hugger Models 505 and 750 met regulatory requirements and are consistent with industry standards. There is no basis to find the labeling misbranded.

The Complaint and Dr. David's report allege 3M/Arizant had a duty to warn physicians and users of the risks, dangers, and adverse side effects of the Bair Huggers. The regulatory vehicle for providing instructions for use is the labeling provided with the device.

FDA regulations define the requirements for medical device labeling.[114] The FDA device labeling regulation divides devices into either over-the-counter (OTC) lay use devices or prescription devices. OTC device labeling must have "adequate directions for use" as specified in the regulation.[115] Prescription devices are exempt from adequate directions for use provided the prescription devices are properly labeled for health care professionals, they are in the possession and used under the supervision of a practitioner licensed by law to use the device, and they are prescribed by practitioners licensed in the respective state.[116] The Bair Hugger devices are prescription use only devices.

[114] Device Labeling, 21 CFR Part 801.

[115] Adequate Directions for Use, 21 CFR §801.5.

[116] Prescription devices, 21 CFR §801.109.

The labeling for a prescription device must contain information specified in the prescription labeling subpart of the device labeling regulation.[117] Prescription labeling must include a cautionary statement, the method of use of the device, as well as information for use such as indications, contraindications, side effects and precautions. A manufacturer may periodically update labeling to reflect significant new risk information when it is appropriate. . . Typically, significant new risk information can be a clinically important and distinct new type of risk or a significant increase in degree of risk.

Medical device labeling regulations do not mandate patient labeling, e.g., patient brochures or a patient insert. FDA can make patient labeling for a specific device a requirement only three ways, by a regulation promulgated under 21 CFR 801 part H, by a Premarket Application Approval order for a Class III device, or by a special control for a Class II device. FDA has not exercised any of these options to require patient labeling for Class II thermal regulating systems like the Bair Hugger devices.

Model 505 Labeling

I examined several versions of the labeling for the Bair Hugger Patient Warming System Model 505 in distribution after the clearance of the 501(k), including the following:[118]

Operators Manuals:

Doc. No. 102306H (original 510(k)), Blanket Labeling and other device labeling included. Amended by Augustine Medical letter dated May 10, 2996.

102306K: 12/1996

[117] Prescription labeling may also be called Instructions for Use or Package Inserts.

[118] 102306H: 3MBH00047301-00047384, 102306K: 3MBH00047064-00047088, 200977E: 3MBH00105180-000105193, 200977F: 3MBH00129876-00129890, 202431A: 3MBH01849567-01849585.

200977E: 2009

200977F: 4/2011

202431A: 5/2013

The labeling submitted in the 510(k) includes the requisite precautionary information (e.g., contraindications, warnings, precautions, important information), instructions for use of the device, use of blankets, maintenance, cleaning, and specifications. The warnings were amended prior to FDA clearance.

The 102306K labeling has some modifications including, for example, the use of the device name of Total Temperature Management System, discussion of hypothermia at the beginning of the manual, reformatting of instructions for use information. hose options and expanded specifications with the specification for the filtration system (0.2µm level).

The 200977E labeling is a multi-language version including an English version. The format is updated. The specifications include the same filtration system specifications and a recommended filter change of every 6 months or 500 hours of use. Safety information is updated at the end of the manual.

The 200977F version again is a multi-language version similar to the E version noted above and has expanded warnings. The 2024131A version is similar to the version 200977F and has expanded warnings and cautions

Model 750 Labeling

I examined many versions of the labeling for the Bair Hugger Total Temperature Management System Model 750 in distribution after clearance of the 510(k), including the following:[119]

Operators Manuals:

200594A dated 03/03.

200594D dated 05/05.

200742E dated 05/05.

200742F dated 5/2008

200742H undated

Service Manuals:

102346C dated 09/02

200595A dated 03/03

200595B dated 08/03

200595E dated 05/05

200595G dated 07/2009

I examined the draft labeling for the Model 750 in the cleared 510(k) from 2000 and note some differences with the labeling provided after initial distribution.[120] In no case do I think that the differences are substantial changes. The differences include the following:

[119] 200594D: 3MBH00044582-00044598, 200595E: 3MBH00044599-00044626, 200742E:3MBH00044655-00044864, 200595G: 3MBH00044489-44519, 200742H:3MBH00044865-00044882, 200594A:3MBH00044900-00044917, 200595A:3MBH00044918-00044947, 102345D:3MBH00044580-00044581. 102346C:3MBH00044199-00044228, 200595B:3MBH00044165-00044193.

[120] 3MBH00047037-00047057.

1. The 2000 draft labeling describes hypothermia.

2. The 2000 draft indications are more specific in regard to hypothermic symptoms. In addition introductory information states:

> Examples of current applications for the Bair Hugger Total Temperature Management system are post anesthesia care units (PACU), recovery rooms, operating rooms, emergency departments, obstetrical suites, and intensive care areas.

The comparison of substantial equivalence also refers to OR use as follows:[121]

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Intended Use	Patient warming	Patient warming
Clinical areas for device use	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients

3. The Model 241 fluid device warning in the 2000 draft is not identical to the recent labeling.

4. There is a warning on mounting the device in the 2000 draft labeling and it was changed to a Caution.

5. There is more information on the Model 241 warmer and blankets in the 2000 draft labeling.

6. "Important Information" in the 2000 draft labeling is relocated in the recent labeling.

[121] 3MBH00047009.

7. The "Read Before Servicing" information in the original draft labeling is restructured in the recent labeling.

As noted earlier in this report, FDA cleared two labeling changes for the Bair Hugger in submissions K041686 and K053645, based on my search of FDA's 510(k) database and litigation production.[122] The K041686 record shows this was a special 510(k) "to include results and recommendations regarding the benefits of forced air warming from published studies by a number of medical experts."[123] Similarly, the second special 510(k) submission, K053645, was to add labeling claims.[124] It is clear from the record that FDA reviewed the claims thoroughly and requested additional information, which Arizant submitted.

As I stated I do not believe that the differences in labeling between the original draft labeling and the marketed devices are significant. There is no need to describe hypothermia in detail in the Bair Hugger labeling since the device is for prescription use only. Users should refer to labeling for the Model 241 fluid warmer and blankets. The other changes are minor edits of information.

I examined the labeling for blankets used with the Bair Hugger. The labeling states words such as the following:[125]

2 Remove the backing from the surgical tape and tape the blanket to the patient. The surgical tape prevents air from flowing toward the surgical site (see Figure B).

[122] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

[123] 3MBH00047643.

[124] 3MBH00047738.

[125] Blanket labeling example: 3MBH00045472-45474.

This Complaint alleges that Bair Huggers caused surgical site infections. Expert for Plaintiffs, Dr. Yadin David, opines on page 41 of his report that "...the removal of an airborne contamination warning from the Bair Hugger [labeling] makes the device unreasonably dangerous." He notes that the Model 200 had a warning and the 500 and 700 series devices do not have such a warning. To address this I evaluated factors related to the air filtering in the Bair Hugger Temperature Management System.

Labeling instructions refer to isolation of the blankets from the surgical site using tape.[126] The air supplied to the blankets is filtered by a 0.2µm filter. The material of the disposable blankets themselves may afford some degree of air filtering although the filtering contribution of the blanket material is not established in the litigation records.

A 3M Risk Management Report indicates a low risk level for the potential hazard of surgical site infection.[127] Mr. Van Duren's testimony was consistent with this 3M risk analysis when asked about the absence of the prior Model 200 labeling statement as follows:[128]

And it's very likely that the hazard analysis that occurred subsequent to the development of this device recognized that the risk index was either too low or zero and removed that warning from the labeling.

[126] 3MBH00047031 and 3MBH00047032-00047033.

[127] 3MBH00553184.

[128] Van Duren deposition, 3/7/17, Page 314:14-18.

Dr. David also includes in his report what he characterizes as a Warning on airborne contamination, from labeling for a product called Mistral-Air Plus.[129] The Bair Huger Model 750 is a predicate for the Mistral-Air Plus device.[130]

The Mistral-Air Plus statement is not a Warning but rather stated in Mistral labeling to be a "Safety Precaution," therefore, Dr. David's reference to FDA guidance on Warnings regarding the Mistral-Air Plus labeling is misplaced. The Mistral-Air Plus Safety Precaution states:

The Mistral-Air® Plus warming unit is fitted with an air filter; however airborne contamination should be taken into consideration when using the warming system.

A precaution is a statement of special care to be exercised by the practitioner for safe and effective use of the device.[131] The above Mistral-Air Safety Precaution statement is unclear concerning what considerations should be made regarding airborne contamination and does not provide the user with actionable steps to take. The Mistral-Air brochure and accessory usage indicate the Mistral-Air can be used in an operating room. However, no Mistral labeling information provides factors to consider when using the device in an operating room environment.

According to FDA, a Warning in labeling may be appropriate if there is reasonable evidence of an association of a serious hazard with the use of the device.[132] I do not believe that a Warning in the Models 505 and 750 labeling regarding an infection risk for the Arizant forced air warming devices and accessories when used in operating rooms was warranted due to: (1)

[129] See also http://www.the37company.com/product_overview/forced_air_warming_1/warming_unit.

[130] https://www.accessdata.fda.gov/cdrh_docs/pdf10/K101705.pdf. Page 41 of David report.

[131] K91-1 FDA guidance.

[132] FDA Guidance, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm.

the paucity of MDR reports pertaining to infection until Dr. Augustine induced reports began in 2015 and 2016 that I discuss in this report, (2) the lack of a direct causal relationship of infections to forced air warming that Dr. David acknowledges in his report (p. 31), (3) the analysis of risk of surgical site infections in the 3M Risk Management Report noted above, and (4) the existing blanket and taping design and blanket labeling, and filter mitigations described above .

I find as I describe above that the draft labeling in the original 510(k) and the labeling in the subsequent versions of the Model 750 all meet the FDA prescription labeling requirements of 21 CFR §801.109. The labeling for the Model 505 also meets the regulatory requirements for prescription labeling. The labeling is also consistent with industry standards in form and content.

As noted above, the labeling for the blankets includes taping instructions to prevent airflow to the surgical site. The existing Warnings are consistent with predicates and the current published data and are acceptable.

FDA never requested any modifications or additions to the labeling for the Models 505 or 750 or any other Bair Hugger model at any point in time.

Given that the Bair Hugger Models 505 and 750 labeling conforms to the prescription device regulation I believe there is no basis to allege that it is misbranded.[133] Dr. David does not opine that the Bair Hugger labeling contains false or misleading information and I did not identify any such information in my evaluation of the labeling.

[133] Misbranding and adulteration and other prohibited acts under the FDCA are charges brought by FDA through the Department of Justice based on evidence described in FDA's Regulatory Procedures Manual. The charges are subject to due process and are adjudicated in federal court.

9. It is my opinion that a 2010 Warning Letter from FDA to Arizant, Inc. did not result in any observation regarding MDRs for complaints of infection and the findings in the letter which were quickly resolved does not undermine the reasonable assurance of safety and effectiveness of the Bair Hugger.

On June 7, 2010, FDA issued a Warning Letter, under my signature as Director of CDRH Compliance, to Arizant Inc. based on an inspection of Arizant's Eden Prairie, Minnesota facility from November 30, 2009 to January 6, 2010.[134] This inspection is one of the regulatory events Dr. David finds to be troubling. I do not find the inspection to be troubling whatsoever but instead a rather typical directed inspection with quick resolution of the citations in the FDA letter.

The 2010 Warning Letter cited four violations of the Medical Device Reporting regulation, 21 CFR Part 803, and a violation of the Corrections and Removal regulation, 21 CFR 806. The letter included examples of each violation and an analysis of Arizant's January 20, 2010 response to the Form 483 issued to Arizant at the close of the inspection.[135] The letter also includes comments on an Arizant complaint management procedure. Arizant Inc. adequately responded to FDA's Warning Letter and FDA closed out the inspection and Warning Letter on July 27, 2010.[136]

The Warning Letter cites no violations of the FDA quality system regulation, 21 CFR Part 820. As I noted earlier in this report the Quality System regulation is intended to ensure that

[134] http://wayback.archive-it.org/7993/20161023102048/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm217747.htm..

[135] Form 483 is a list of observations made by the FDA inspector during the inspection and presented to the most responsible person of the inspected facility at the close of the inspection. The observations are not violations but form the basis for an Establishment Inspection Report that includes recommended violations. The final decision on violations rests with the Director of Compliance, CDRH or as delegated by him/her to District Directors. See FDA Regulatory Procedures Manual, http://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/default.htm.

[136] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm235588.htm.

finished devices will be safe and effective.[137] The Warning Letter did not lead to FDA enforcement action against Arizant Inc. based on my review of FDA enforcement actions on FDA's web site.[138]

At the end of the inspection in January 2010 Arizant responded quickly to the five observations, correcting four observations before FDA issued the Warning Letter.[139] Two observations related to filing an MDR report, which Arizant submitted. Arizant adequately responded to the one Corrections and Removal observation. Arizant submitted to FDA a report of a correction and removal (i.e., 806 Report) for power cords manufactured and supplied by Electri-Cord Manufacturing Corporation and used on Arizant devices. No Arizant manufactured components were implicated, based on my review of the FDA recall database.[140]

One issue in the FDA inspection dealt with the reporting of MDRs for burns. FDA changed its opinion on reporting burns between the early 90s and the 2009-2010 date of the inspection. The inspection report notes the following:[141]

> and he provided me with a letter addressed to the U.S. Food and Drug Administration dated May 7, 1992 (Exhibit 19). The letter outlines burn severity from first to third degree. Arizant's policy has been to report only 3rd degree burns.
>
> CALL 63505 (Exhibit 20) was received on 04/13/06 and involved a patient who sustained 2nd degree burns; the patient was subsequently moved from the surgery center to the ER where the burns were treated. An Initial Adverse Event/Injury Report form, AMI148, was completed by an Arizant customer service rep (page 2). In addition to the hospital reporting the incident, on May 18, 2006 the patient personally contacted Arizant via the website contact feature. The patient stated she 'ended with third degree burn on my left breast" and inquired about the product (page 4).
>
> [NOTE: During the inspection, I double-checked my interpretation of the regulation with Linda Hoffman, Consumer Safety Officer, FDA/CDRH/Division of Surveillance Systems. She confirmed that this event should have been reported.]

[137] 21 CFR §820.1(a).

[138] FDA Enforcement Reports, http://www.fda.gov/safety/recalls/enforcementreports/.

[139] establishment inspection report, 3MBH00048067-00048085.

[140] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm.

[141] 3MBH00048075.

Page 4 of the Establishment Inspection Report (EIR) for this inspection refers to the Bair Hugger containing a 0.2µm HEPA filter.[142] The EIR does not describe the basis for this statement. There is no evidence that Arizant mislead FDA on this issue. As noted in this report, FDA was informed of the status of the filter in the Model 750. Since this was a directed inspection to evaluate complaints and MDR reporting and not to evaluate the design of the device the characteristics of the filter are really not germane to the inspection in any case. I discuss the published papers provided to the inspector in a subsequent comment on Dr. David's report.

I do not believe that the Warning Letter undermines the safety and effectiveness of the Bair Hugger. Warning Letters are advisory actions allowing companies the opportunity to take voluntary action to improve their quality management program.[143] Arizant responded to the issues in the letter by addressing certain limited MDR issues, correcting a complaint procedure, and submitting 806 reports for power cords. If FDA believed the Bair Hugger was a risk to health or warranted corrective action FDA could have proceeded to an enforcement action. FDA did not do so. The Bair Hugger continues to be marketed by 3M, based on my review of 3M's web site, and 3M is legitimately permitted to do so by the 510(k) clearance orders from FDA.

10. It is my opinion that in a 2012 Warning Letter to Augustine Biomedical & Design, LLC the FDA repudiated claims against the Bair Hugger made by Augustine Biomedical & Design, LLC.

In a Warning Letter dated July 27, 2012, FDA informed Augustine Biomedical & Design, LLC that an infection reduction claim and comparative claim "HOTDOG IS SAFER" for its Hot Dog Patient Warming System represented a major change or modification to the intended use of

[142] 3MBH00048067-00048085.

[143] See FDA Regulatory Procedures Manual, Section 4-1.

the device.[144] FDA informed Augustine Biomedical & Design, LLC that the Hot Dog Patient Warming System was adulterated and misbranded and such a change required submission of a new 510(k) for the Hot Dog Patient Warming System and the claims require submission of clinical data to support the claims.

The claims found by FDA to be violative refer to the Hot Dog Patient Warming System advantages compared to forced-air warming, air-free warming, and the statement "Bair Hugger contaminates sterile field: Waste hot air convection currents transport contaminated air into the surgical site. Air-free warming has no such effect. Researchers concluded: Airfree warming, therefore, is recommended over forced-air warming for orthopedic procedures."

The FDA web site indicates a response letter by Augustine Biomedical & Design, LLC was not posted and there is no FDA close out posted on the web site. I see no FDA-cleared 510(k) for the Hot Dog Patient Warming System since 11/23/11.[145] Therefore, I must conclude that FDA still has not agreed with the claims.

The claims noted above made by Augustine Biomedical & Design, LLC against the Bair Hugger run counter to the preponderance of evidence of the safety and effectiveness data and information previously submitted by Augustine Medical Inc. to FDA in the 510(k)s for the Model 750[146] in the medical literature previously referenced in this report, the ECRI analysis and as provided to FDA in 2015.[147]

[144] http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm315670.htm.

[145] Search 5/11/17, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

[146] See K041686 and K053645 and FDA review of the last submission.

[147] 3MBH01630129-01630651. ECRI analysis in this document as well.

In my review of MDRs in my report I identified MDRs for the Hot Dog related to overheating of the device and a report of patient injury. This is further evidence undermining the alleged comparative superiority of the Hot Dog over the Bair Hugger.

11. It is my opinion that CDC/HICPAC and FDA meeting discussions concerning a heater-cooler device are unrelated to forced air warming devices.

Dr. David refers to a 2015 Centers for Disease Control and Prevention/Healthcare Infection Control Advisory Committee meeting in his allegations regarding the Bair Hugger (Page 43). I believe his characterization of a statement from the meeting must be considered in context to understand that the focus of the CDC/HICPAC was not on forced air warming devices.

In the meeting of the CDC/HICPAC in November 2015 there was a presentation by Drs. Perz and Bell, two CDC employees who were not members of HICPAC entitled "Nontuberculous Mycobacterium Infections Associated with Heater-Cooler devices."[148] The particular heater-cooler device type in question circulates temperature-regulated water in cardiovascular surgery and is a different classified type of device compared to temperature regulating devices like the Bair Hugger. The presentation section of the report to HICPAC on the heater-cooler device type includes a statement without attribution, "The heater-cooler unit appears to be harmless from an infection perspective, but the water overflow bottle is likely rarely, if ever, sanitized and is situated in front of a fan. Nothing that blows air should be in an operating theater, if possible." This statement is not in the discussion section of the report and is

[148] https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting_Summary_Final-508.pdf.

not characterized as a conclusion of HICPAC as stated in the undated and untitled report by Dr. William Jarvis, expert for Plaintiffs.

FDA's posted a safety communication on circulating water heater devices on October 25, 2015.[149] FDA posted no safety alert pertaining to other types of temperature regulating devices.

In March 2016 the CDC/HICPAC was brought up to date by an FDA employee on its activities pertaining to the heater-cooler devices used in cardiac surgery. The HICPAC minutes state, in part:[150]

Many challenges are associated with this multi-factorial problem.

- It is not feasible for these devices to be sterile.
- There are many OR environment considerations as well as hospital infection control procedure and patient considerations.
- NTM is fairly ubiquitous and, locating the source of NTM leading to infection is challenging.
- It is not clear whether there is an acceptable level of contamination at which a device can still be used safely. For instance, if aerosols can be reduced or eliminated from the unit, can the circuit water safely maintain some level of contamination?
- There are challenges associated with validating the cleaning and disinfection procedures and what might represent "worst-case" testing. It is not clear how real-world use can be mimicked in laboratories for testing. Which microbe or microbes should be monitored and what is an acceptable output or contamination level?
- Heater-cooler units are a capital expense, currently with a service life of approximately 10 years. If they become contaminated beyond an acceptable level, alternatives are needed for these lifesaving devices. Unless contaminated units can be reliably disinfected, purchase of new units may be necessary.
- Patient notification is a challenge, including what patients should be told regarding the risks prior to a procedure and whether patients who have already undergone a cardiac surgery should be stratified and notified based on a reliable risk scale.

FDA posted a web site pertaining to the heater-cooler devices used in cardiovascular surgery. It does not pertain to temperature regulating devices like the Bair Hugger.[151] FDA

[149] https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm.

[150] https://www.cdc.gov/hicpac/pdf/mm/March-31-2016-HICPAC-Meeting-Summary-FINAL.pdf.

posted a safety communication on June 1, 2016, regarding one specific heater-cooler device used in cardiovascular surgery and updated that communication on October 13, 2016.[152]

An update at the July 2016 meeting of CDC/HICPAC continued to focus on the cardiovascular heater-cooler units discussed in prior meetings.[153] CDC's MMWR Report dated October 14, 2016 continued to focus solely on the heater-cooler devices used in cardiovascular surgery.[154]

There is no substantive discussion in the CDC/HICPAC minutes of risks posed by other types of temperature regulating devices like the Bair Hugger.

12. It is my opinion that Arizant appropriately monitored the literature and other sources of information regarding its products and investigated concerns regarding its device in accordance with FDA post market procedures and industry practice. Arizant also conducted field actions based upon postmarket information as appropriate.

It is the responsibility of a manufacturer to evaluate and investigate complaints regarding their device.[155] A manufacturer is also responsible for monitoring information regarding its device and to take corrective and preventive action when necessary to mitigate device risks.[156] 3M/Arizant complied with their postmarket regulatory duties in a manner consistent with a reasonable and prudent manufacturer.

Dr. Augustine made various claims against the Bair Hugger devices after he formed a

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[151] https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/default.htm.

[152] https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm

[153] https://www.cdc.gov/hicpac/pdf/mm/July-14-15-2016-HICPAC-Summary-FINAL.pdf.

[154] https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w.

[155] Complaint files, 21 CFR §820.198.

[156] Corrective and preventive action, 21 CFR §820.100.

new, competing company.[157] In a regulatory context I would characterize his assertions concerning forced air warming as complaints. There were also publications, by far mostly supportive and some adverse to forced air technology.[158] I have reviewed the correspondence between Dr. Augustine, Arizant and 3M following his departure from Arizant.[159] I have also reviewed marketing claims and scientific literature supported by Dr. Augustine and his company Augustine Biomedical and Design and for Arizant.[160]

Arizant evaluated the "Blowing Air is Risky" campaign by Dr. Augustine.[161] Arizant notes the following in its analysis:

> **Summary:** ABAD has promotional literature and a new web site (www.blowingairisrisky.com) that makes claims about forced air warming. They say that 1) warming unit haves internal contamination, 2) this contamination is blown onto patients, 3) the contamination is uncleanable, and 4) the units cause "noise pollution. These assertions are based on sloppy or deceptive readings of medical literature, unpublished research of their own, and video-based product demonstrations. We have extensive research and real-world experience refuting these claims.

Based on my review of the documents concerning Dr. Augustine allegations, 3M/Arizant responded appropriately in evaluating the merits of Dr. Augustine's claims of contamination and infection caused by the Bair Hugger. As I discuss in this report, 3M/Arizant ultimately came to the conclusion that Dr. Augustine's claims were not scientifically supported. The FDA's 2012 Warning Letter to Dr. Augustine I discuss in this report affirms the reasonableness of the company's conclusions with respect to Dr. Augustine's claims.

In no case did I find evidence of Arizant disregarding any other complaints or

[157] Example, 3MBH00001186-00001188.

[158] Studies and associated emails distributed throughout the productions: Examples 3MBH00001701-00001807, 3MBH00002393-0002429, 3MBH00005698-00005702.

[159] Examples, 3MBH00005676-00005677, 3MBH00043532, 3MBH00005688, 3MBH00005693-00005697, 3MBH00030543-00030549, 3MBH00030552-00030556, 3MBH00034432-00034438, 3MBH00038869-00038871.

[160] Examples, 3MBH00040177, 3MBH00078167-00078168, 3MBH00078181-00078184.

[161] Example, 3MBH00001692.

information they became aware of regarding their device or the technology upon which it is based. Instead, it appears from my review of the records, that they took these complaints and information seriously and responsibly investigated them.

There are several additional examples of Arizant's follow up regarding allegations of infections. Arizant followed up with Dr. Beavers on her article in the Kentucky Epidemiological Notes and reports in 2007 cited by an Augustine promotional piece. Dr. Beaver stated the following:[162]

> I am writing to clarify some points made in an article I wrote for the *Kentucky Epidemiologic Notes & Reports* in March, 207. In the article I discussed our findings of investigations we performed into outbreaks of *Acinetobacter* at two acute-care hospitals in Kentucky. As you may know, during such investigations we evaluate many factors which may be associated with infection. Therefore, during our investigation we collected data to evaluate whether forced air systems such as Bair Huggers were associated with *Acinetobacter* infection. We did not find an association between *Acinetobacter* infection and Bair Hugger or forced air system use at either facility.
>
> In addition, the Falagas article cited in the paper does not describe forced air systems such as Bair Huggers to be infection reservoirs. The important point of the article and investigation we performed was that a variety of items used during care of ill patients may become contaminated with *Acinetobacter* or other microorganisms. In this investigation, for example, mechanical ventilation was associated with Acinetobacter infection. Therefore, in caring for hospitalized patients, the most important means of preventing infection is to practice good infection control procedures such as hand-washing and environmental cleaning. Conversely, we found no evidence that avoidance of the use of products such as forced air systems would prevent infection with *Acinetobacter*.

Arizant interacted with the British regulators concerning alleged adverse performance of forced air warming.[163] They sent the British regulators a detailed letter dated August 7, 2008, concerning Dr. Augustine's claims made to NICE.[164]

Arizant corresponded with its customers regarding concerns about use of the Bair Hugger. One hospital publicly disputed Dr. Augustine's allegations that the Bair Hugger could lead to increased infections.[165]

Arizant is required by regulation to submit reports of corrections and removals to FDA.

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[162] Augustine article 3MBH00001186-00001188. Dr. Beavers paper, 3MBH00000932-00000937, Dr. Beavers response 3MBH00000930.

[163] 3MBH00002104-00002188.

[164] 3MBH00002183-00002186.

[165] Examples, 3MBH00001526 and 3MBH00001532.

A correction is when a manufacturer makes a change to a device while keeping it at its point of use and a removal is a retrieval of a device in both cases in order to reduce a risk to health or to remedy a violation of FDA law or regulations.[166] A correction or removal may be a recall and FDA classifies recalls. There are three classes of recalls, Class I, II, or III, with Class I being the most serious. FDA defines a Class II recall as "a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."[167] FDA posts recall actions on its web site. So, any voluntary recall actions by Arizant classified by FDA can be identified.

I examined the FDA recall database[168] using the terms "Arizant" and "3M."[169] The search revealed seven recall listings. One recall was a 2005 Class II recall for the Model 555 pediatric blanket.[170] Another recall with two listings was a 2007 Class II recall for Ranger warming sets.[171] The third recall with four listings was in 2010 for power cords.[172] There are no recalls listed for the Models 505 or 750.

The above are but a few examples of many appropriate actions by Arizant to respond to concerns regarding their devices. In sum, I think that Arizant properly reacted to the concerns of customers and to Dr. Augustine's claims in a reasonable and prudent manner according to FDA postmarket requirements. I am not aware of any representations made by 3M or Arizant with

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[166] 21 CFR Part 806.

[167] 21 CFR §7.3(m)(2).

[168] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm.

[169] Search dated 4/21/17.

[170] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=37753.

[171] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=53634 and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=53633.

[172] first of four listed, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=88575.

regard to the Bair Hugger device that misrepresented the safety of the device. As I document above Arizant also conducted field actions as appropriate based on postmarket information.

13. Additional rebuttal to the opinions in the report by Dr. Yadin David

Dr. Yadin David submitted an undated report on behalf of Plaintiffs. I have commented on some aspects of his report in my foregoing opinions. This section includes additional rebuttal to his opinions.

First, I wish to disclose my prior interactions with Dr. David while I was an employee of the FDA. I interacted with Dr. David for a period of time when I was the Director of the Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGID), Office of Device Evaluation, as the division was called prior to my appointment as the Director, Office of Compliance, Center for Devices and Radiological Health in 2003. In my role as DAGID Division Director I reviewed candidates for new committee member appointments to the FDA advisory committee panels associated with the devices evaluated in DAGID. Medical device committee members provide independent advice to FDA on issues related to medical devices. The committee members are technically qualified experts in aspects of their field.[173] They are not appointed based on regulatory expertise. Regulatory advice and counsel at panel meetings is provided by the panel executive secretary, an FDA employee, and by the attending FDA division manager seated with the panel.

If my memory serves me well, FDA appointed Dr. David to the General Hospital Advisory Committee Panel during my tenure as DAGID Director. The Device Good Manufacturing Practice Advisory Committee (GMP Committee) he refers to on page 3 of his

[173] Advisory Committees, http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ucm117646.htm.

report is an advisory committee associated with the Office of Compliance, CDRH. The GMP Committee was inactive from approximately 1995 until 2013 when in April 2013 FDA asked the GMP Committee to evaluate the quality system regulation and the issue of meeting the challenges of extreme weather. Dr. David was not a member of the GMP Committee at that meeting.[174] There have been no meetings of the GMP Committee since April 2013. He was appointed Chair of the GMP Committee with a term beginning 12/10/2014.[175] As I recall, I had no interactions with him while I was Director of the Office of Compliance, CDRH from 2003 until my retirement in 2011.

1. Dr. David characterizes his report as a Hazard Analysis and discusses medical device hazard analysis and risk mitigation on page 5 of his report. It may be implied in Dr. David's report that all risks require exhaustive mitigation. This is not the case. Risks that are acceptable given the existing risk control measures, i.e., the severity and probability are within predetermined acceptable limits, do not require additional mitigation.[176]

Furthermore, I do not find Dr. David's Hazard Analysis to be in a form or manner of an industry standard medical device hazard analysis consisting of a risk assessment and risk control evaluation. It does not contain a systematic identification of characteristics related to the safety of the Bair Hugger, identification of all reasonably foreseeable hazards, estimation of risks, an evaluation of risk reduction when required for all hazardous situations by predetermined criteria and quantitative methodology, e.g., FMEAs, FTAs, an appropriate and practicable risk control

[174] GMP Committee Roster 4/11/2013, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/DeviceGoodManufacturingPracticeAdvisoryCommittee/UCM347410.pdf

[175] GMP Committee Roster, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/DeviceGoodManufacturingPracticeAdvisoryCommittee/ucm124607.htm

[176] See ISO 14971, Section 6, Risk Control.

option analysis based on valid scientific principles, residual risk analysis, and risk/benefit analysis.[177] Instead it is a qualitative expert report on the use of the Bair Hugger in orthopedic surgery commenting and based on the regulatory process, FDA inspections, his practice of assessment of technology, selected publications, and other aspects.

2. On page 5 he refers to the principle of safety and the Hippocratic Oath. What is relevant to this litigation is the definition of "safe" as described in FDA regulation. It is the FDA standard upon which FDA determines the safety of the Bair Hugger and the standard a device must meet. While Dr. David focuses almost entirely on risk in his report the determination of safety is an assessment of benefit/risk and the absence of unreasonable risk. I do not see assessment of risk/benefit in his report per the regulatory definition of safe. He ignores the benefit side of the equation. The FDA definition states:[178]

> There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

3. On pages 6-16 Dr. David discusses his laboratory process for assessing the "basic operation and mechanisms" of a Model 750 device he purchased on e-Bay.com. He also states "his investigation was to examine a Bair Hugger from a biomedical engineering perspective to determine if the design and function of the device posed a risk to patient safety." He states two

[177] See ISO 14971.

[178] 21 CFR §860.7.

ways the Bair Hugger could pose a risk, i.e., (1) disruption of the OR ventilation system and (2) bacteria from the device being introduced into the operating room currents. The conclusions of his report cannot rely on his examination of the e-Bay device because he did not perform any disruption of air flow study or bacterial examination of the device and its outflow in a simulated OR with the device used as intended. Any studies would not be valid in any case since the device he obtained could not be established as representing a serviced device currently in use in a hospital OR or otherwise obtained from the manufacturer for immediate use in an OR.

His report does not include any details of the protocols and test methodologies he employed nor the location of his examination so his findings must be discounted.

His examination does not meet the requirements for control of samples for examination and investigation requirements in the FDA Investigations Operations Manual.[179] Therefore, his examination and resulting conclusions based on his examination would be rejected as a basis for possible enforcement action by FDA.

4. I agree with Dr. David on page 16 that risk classification and controls "insure the safety and effectiveness of the device." He discusses Class III devices that are subject to "rigorous approval" but he does not assess in his report the contents of the 510(k)s for the Bair Hugger Models 505 and 750 that are Class II devices cleared by the FDA and are therefore controls to "insure the safety and effectiveness of the device."

5. Dr. David refers on page 18 to the General Accounting Office and Institute of Medicine reports that made statements such as "FDA lacks the capacity to provide adequate review and clearance oversight. . . ." In regard to medical device evaluation and enforcement I disagree with this statement. In my experience while a manager in the CDRH Office of Device Evaluation and

[179] https://www.fda.gov/ICECI/inspections/IOM/default.htm.

the CDRH Office of Compliance for the time period 1990 through 2010 I am unaware of a lack of resources in those offices preventing or limiting FDA's ability to properly and effectively promote and protect the public health. As workload changed, FDA was quick to redirect resources to the Office of Device Evaluation and the Office of Compliance from other offices in order to maintain necessary staffing and expertise. FDA supplements its staff with the expertise of its Advisory Committee, fellows, and other special government employees.

Dr. David also states that "it is the manufacturer's responsibility to ensure its devices are safe, labeled and marketed in accordance with the approved or cleared indications for use." He also states "FDA relies on the assurances of the manufacturer that appropriate performance testing and validation has occurred." This is not accurate. FDA has a corresponding responsibility to ensure that devices on the market are safe and effective. His report and mine refer to FDA's continuous oversight of Augustine Medical and 3M/Arizant throughout the life cycle of the Bair Hugger devices including, for example, premarket evaluations, facility inspections, Warning Letters, and postmarket evaluations of trade complaints submitted to FDA by both Dr. Augustine and 3M/Arizant.

6. On page 19 Dr. David refers to the Least Burdensome Provisions and their application to 510(k)s. In fact, these provisions apply to both 510(k) and PMA devices.[180] While FDA's evaluation of substantial equivalence is the focus of a 510(k) review FDA can request any information it requires in order to render a decision on equivalence and can assess the impact of evolving science, medicine and engineering on the evaluation of equivalence.

7. On page 19 he begins a discussion on the Bair Hugger's 510(k) clearance history. His comments display a fundamental lack of knowledge of the 510(k) process.

[180] https://www.fda.gov/RegulatoryInformation/Guidances/ucm085994.htm.

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He refers to the Sweetland Bed Warmer predicate identified in the 510(k) for the Bair Hugger Patient Warming System cleared by FDA in 1987 (K873745).[181] This Bair Hugger model (Series 200) was intended for postoperative patient warming using a Bair Hugger Cover on the patient. He questions the validity of the Bair Hugger 500 and 700 series models use in operating rooms given that the Sweetland device and Model 200 were not labeled for use in operating rooms. Dr. Yadin states that the Sweetland Bed Warmer "was never used as a means to create normothermia during surgical procedures, as later Bair Hugger models were." He also mentions changes in technology in the Bair Hugger devices.

The predicate for the Model 500 is the Patient Warming System Model 200 (K873745) in which Sweetland is identified. The predicate for the Model 505 is the Model 500.[182] The 510(k) submission for the Model 500 included valid scientific evidence of the Bair Hugger's use in operating rooms.[183] The 510(k) for the Model 505 clearly states that one intended setting where the Model 505 could be used is in operating rooms.[184]

Contrary to Dr. David's belief, the Sweetland device is a legitimate predicate in the lineage of the Models 500, 505 and 750. The change in the Bair Hugger claims, the clinical usage of the Bair Hugger in operating rooms, and technological changes of the Bair Huggers over time were all legitimately enabled by 510(k) clearances.

The intended use of the Bair Huggers has actually not changed since the clearance of the 510(k) for a Model 200 series device. The intended use of Bair Huggers has always been

[181] 3MBH00047858-00047864 and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K873745.

[182] 3MBH00047382-00047383. Model 505 is predicate for Model 750.

[183] 3MBH00047446.

[184] 3MBH00047197.

warming of patients. FDA has made clear the meaning of the term intended use. FDA guidance states:[185]

> For purposes of substantial equivalence, the term **intended use** means the general purpose of the device or its function, and encompasses the indications for use. The term **indications for use**, as defined in 21 CFR 814.20(b)(3)(i), describes the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.[22] The intended use of a device is one criterion that determines whether a device can be cleared for marketing through the 510(k) process or must be evaluated in a PMA (or alternative submission type), or if appropriate, a *De Novo* request. The proposed labeling in a 510(k) is used to determine a device's intended use (Section 513(i)(1)(E) of the FD&C Act). The indications for use statement in a 510(k) is also a factor in determining a device's intended use. Consistency between the indications for use statement and the proposed labeling will facilitate the review of the 510(k).
>
> A finding of substantial equivalence means that the indications for use of the new device fall within the intended use of the predicate device and, therefore, the two devices have the same intended use. For devices with general indications for use that do not specify a disease, condition, or population (or an anatomical site from which a disease state or population may be inferred), the indications for use and intended use are the same. Such indications for use are referred to as "tool type" indications for use. Examples of devices with "tool type" indications for use include devices such as scalpels, which are often indicated for cutting tissue, or imaging devices, which are often indicated for taking images of the body. A scalpel indicated for removing a particular type of cancerous cell, however, has indications for use specific to the identified disease, condition, or population, and therefore, does not have "tool type" indications for use.
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> ***
>
> While a new device must have the same intended use as a predicate device in order to be SE, the Center does not require that a new device be labeled with precise therapeutic or diagnostic statements identical to those that appear on predicate device labeling in order for the new device to have the same intended use. Label statements may vary. Certain elements of a predicate device's labeled indication may not be critical to its intended therapeutic, diagnostic, prosthetic, surgical, etc., use. The Center's scientific expertise enables it to exercise considerable discretion in construing intended uses in the labeling and promotional materials for predicate and new devices.3/ Thus, a new device with the same intended use as a predicate device may have different specific indication statements, and, as long as these label indications do not introduce questions about safety or effectiveness different from those that were posed by the predicate device's intended use, the new device may be found SE.

As stated above by FDA, an intended use is the general functional purpose of a device. In the case of the Bair Huggers the indication is a "tool type" use. Since the functional or "tool type" purpose, i.e., patient warming, of the Bair Huggers did not change then all the Bair Hugger

[185] 2014 guidance, https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf and 6/30/86 K86-3 guidance superseded by 2014 guidance.

devices were equivalent on this basis. The expansion of clinical settings for use of the Bair Huggers is legitimately encompassed by the Bair Hugger intended use.

The technological characteristics of a new device can change from that of a predicate and FDA can find the new device to be equivalent as long as the differences in characteristics do not raise new types of safety and effectiveness questions, there are accepted methods to assess the changes, and the performance data demonstrates that the new device is equivalent to the predicate. FDA states the following:[186]

> After FDA has determined that a valid predicate device exists for a new device and that both devices have the same intended use, FDA will move to Decision Points 3 and 4 of the Flowchart (see **Appendix A**). In these steps of the 510(k) review process, FDA compares the technological characteristics of the new device and the predicate device to determine whether the new device has the same technological characteristics as the predicate, and if not, whether the different technological characteristics raise different questions of safety and effectiveness.[25] Devices reviewed under the 510(k) program commonly have different technological characteristics from their predicate device(s); however, FDA rarely makes a finding of NSE at Decision Point 4.[26]
>
> ***
>
> If a new device has the same intended use as a predicate device, and there are no technological differences between the new and a predicate device, the new device is SE. If the device has the same intended use and technological differences, but the technological differences could not affect safety or effectiveness, it is SE. If the device has the same intended use and technological differences that could affect safety or effectiveness, the new device may not be SE. Technological differences may include modifications in design, materials, or energy sources; for example, changes in the power levels of electrical surgical instruments, the use of new reagents in in vitro diagnostic devices, the use of new materials in orthopedic implants, and the use of new battery designs in implanted pacemakers. The Center finds devices with new technological features to be NSE when the new feature could adversely affect safety or effectiveness in a way that is consequential under the conditions of intended use.

There was a progression of technological changes in Bair Huggers over time as evidenced in the 510(k)s I identify in this report. None of the technological changes raise new types of safety and effectiveness questions and standards-based or state of the art test methodologies enabled assessment of the changes. The Bair Huggers 510(k)s included evidence that the devices performed as intended, met safety standards and were certified by recognized test facilities.

[186] Id.

There were no FDA Quality System design control requirements prior to 1997, including, for example, the requirements for a manufacturer to establish and maintain a design history file and control of design changes. Therefore, Dr. David cannot retrospectively apply the FDA design control requirements to the development and testing of the Bair Huggers before FDA's transitional enforcement discretion period on design controls expired on June 1, 1998.[187]

Nevertheless, prior to the development of the QS standard and the original version of the International Standard on risk management, ISO 14971, Augustine Medical applied design control and risk management methodologies in development of the Bair Hugger.[188]

8. Beginning on page 19 Dr. David refers to the Model 505 Summary of Safety and Effectiveness.[189] He takes issue with the statement in the Summary and the papers submitted concerning contamination. The Summary, in part, states the following:

> C. Other Safety Concerns:
>
> 1. Contamination. Airborne contamination from air blown intraoperatively across the surgical wound may result in airborne contamination.
>
> Prevention of airborne contamination: All Bair Hugger® Blankets designed for use in the operating room feature a tape barrier which prevent air from migrating toward the surgical site. Additionally, air is filtered through a 0.2 micron filter. Two studies have concluded that the Bair Hugger® 500 Series Units (that have the same air output specifications and the same filter density as the Model 505) do not increase the incidence of microbial or wound contamination[4,5].
>
> ***
>
> 4. Hall, A. Bair Hugger® Warmer Does Not Increase Microbial Contamination in the Operating Room. Abstract presented at the Post Graduate Assembly, New York Society of Anesthesiologists, New York, NY, December 1991.
>
> 5. Zink, RS. Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room. Anesthesiology 77:A1093, 1992 & Anesth Analg, 1993:76;50-3.

[187] Final QS regulation FR Notice, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm.

[188] Risk management and design control procedures, 3MBH02273025-02290677. See also above opinion on design history files.

[189] 3MBH00047382.

FDA cleared the Model 505 on June 17, 1996. The abstract and paper cited in the 510(k) were from 1991 and 1993. The earliest paper cited by Dr. David in his "Review of Literature Finding Risk from the Use of the Bair Hugger" starting on page 27 of his report is from 2002.

He states that "these papers do not provide sufficient clinical validation of the safety of the Bair Hugger 500 series in orthopedic implant surgical procedures, especially in the face of other published research which the Defendant has never provided to the FDA." He does not reference any publications prior to FDA clearance of the Model 505. Publications prior to 1996 providing clinical evidence supporting intraoperative thermoregulation include, for example, those published by Camus, Carli, Sessler, Hynson, Just, Kelley, Kurz, and Giesbrecht.[190]

The Quality System regulation defines design validation as follows:[191]

> *Design validation.* Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

Even though FDA's design control requirements were not in place until 1997 and enforced by FDA until June 1998 as noted above, the 510(k) for the Model 505 included information on Augustine Medical's design control process as follows:[192]

[190] 3MBH01630160-01630195.

[191] 21 CFR §820.30(g).

> **Augustine Medical Design Control Process.** The design for the Bair Hugger® Model 505 Warming Unit was developed in accordance with Augustine Medical Design Control procedures. These procedures are in compliance with Good Manufacturing Practices as well as ISO 9000 standards.
>
> First, an input specification was written for this device based on market information and approved by our Product Development Advisory Board, as described in our design and development procedures. The final design was developed and evaluated by our Warming Unit product team, which comprises individuals from Marketing, Manufacturing, Manufacturing Engineering, Assembly Production, Purchasing, Regulatory Affairs, and Product Development.
>
> Failure Mode Effect and Analysis was performed during the prototype stage. (See Appendix H for more information.) This Unit was tested during the design development stage to ensure that the final design is safe and effective. Final validation testing was also performed on the final design (Appendix H).

The Model 505 510(k) includes safety tests, certifications, and results as noted in this report. The Design History File refers to clinical beta assessment of the devices. These tests, certifications, clinical papers and clinical beta assessments cited above meet the definition of "validation," both under simulation and actual use conditions according to the QS regulation.[193] Therefore, the Model 505 was properly validated, contrary to Dr. David's assertion.

9. On page 22 Dr. David states the engineers "quietly made the decision" to use the M20 media in the Model 750 after the June letter to FDA. The reference is an email from Karl Zgoda to the Cobra group.[194] Dr. David's referenced quote implies that Augustine Medical was required to report the change to FDA which it was not required to do according to regulations because the change is not of a reportable type listed in regulation and guidance.[195]

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[192] 3MBH00047282. See also my opinion on the Model 505 DHF.

[193] A product used in validations need not be the final designed product but the data should be applicable to the design characteristics of the final product.

[194] 3MBH00497304.

[195] 21 CFR Part 807 and FDA guidance on changes to 510(k) devices. To put device engineering changes in perspective there are about 3500 510(k)s submitted per year to FDA. However, there are 6500 medical device companies in the US alone per https://www.selectusa.gov/medical-technology-industry-united-states. Considering on average how many Class II non-exempt devices are made by these companies and foreign importers times a conservative estimate of average engineering changes per year per device I conclude that extremely few engineering changes for Class II non-exempt devices are considered by manufacturers to be significant changes per the 510(k) regulation.

Again Dr. David uses hyperbole to describe the comparison of efficiency between the M10 and M20 media based on an email from Porous Media.[196] The efficiency is less for the M20 compared to the M10 at the stated test conditions but Dr. David does not explain the note in the email that actual efficiency depends on design parameters of the filter. Also, he does not discuss the higher efficiencies against sizes that are also relevant to the operating room.

The test curve for a Model 750 filter that Dr. David reproduces in his report on page 23 shows increasing efficiency of a Model 750 filter up to 95% at 0.8 micron particle size.[197] The document does not describe the test method used by "camfil FARR" and how its method corresponds to the test methods used by Porous Media. Prior to this chart referenced by Dr. David in his report he had referred to a memo from Porous Media indicating a 58% efficiency at 0.3µM.[198] When shown Exhibit 173 Mr. Crowder from Pentair (formerly Porous Media) stated that the 58% efficiency at .3µm in the Porous Media email "...are lower values than was demonstrated by the data sheets from the media supplier."

Camfil's web site has information relevant to Dr. David's assertions regarding the Model 750 filter. Camfil designates MERV 14 filters and certain other non-HEPA filters as "High Efficiency" filters.[199] Mr. Crowder from Pentair testified:[200]

[196] 3MBH00022366.

[197] 3MBH00022367.

[198] Id.

[199] http://www.camfil.us/.

[200] Crowder deposition, 3/16/17, Page 16:7-18.

Q. Okay. If -- if I had, representing to the public, that I had a -- in this case a one-micron filter and it was removing 40 percent of the particles at that size, is it -- is it fair to call that a high-efficiency filter?

A. It could be.

Q. What does the term "highly efficient" mean to you?

A. I'm not aware of a technical definition for "highly efficient." I would, myself, interpret it to be media that's capable of removing very small particulates from airflow.

Therefore, according to these filter industry sources I must assume that Augustine company information stating that the Model 750 filter is "highly efficient" or some variation of that is legitimate.

Camfil provides the following information indicating legitimate use of MERV 14 filters in hospitals (the Bair Hugger filter is MERV 14) and particle sizes where the M20 media is highly efficient:

Air filters commonly applied in health care air conditioning systems have a very high efficiency on removing airborne droplet nuclei. The minimum standard of care for areas of a facility where infected individuals are cared for would have MERV 7 prefiltration and MERV 14 final filtration. Some of these areas would also have an additional stage of HEPA filters.

The initial efficiency of a MERV 14 filter on 1-5 micron size particles is well over 95%.

***

> Other contaminants, by general particle size range, include: bacteria—ranges from 0.30 to 4 microns; droplet nuclei—averages 3 microns; many allergens, fungi and bioaerosols—at least 3 microns; visible dust—10 microns; and a human hair—at least 80 microns in diameter.

10. On page 23 Dr. David refers to a 2003 email regarding a Bair Paws upgrade and Polar Air II.[201] The email states that the filtration level of the Model 505 must be matched by new devices or it must be proven that reduced filtration is safe. He does not disclose the preceding sentence that states, "Filtration of any kind is not required by regulatory standards, however it is expected by many customers. We currently offer sub-HEPA filtration that is the basis of safety claims in the 505's 510(k)." So, a plausible interpretation is that "sub-HEPA" filtration is needed for new devices. The Model 750 has sub-HEPA filtration with an M20 media.

11. On page 23-24, he refers to the letter-to-file and submission requirements for changes. He concludes that changes to the control mechanism, performance specifications, or materials are not being supplied to specifications, all raise new issues of safety and efficacy and require a new 510(k). In the case of the technological change of M10 vs. M20 media there is a change in material but Augustine Medical was the specifications developer and not Porous Media. The M20 media met Augustine Medical's new specification caused by the lack of future supply of M10 by Porous Media.

[201] 3MBH01031246.

FDA K97-1 guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" is not clear on the decision pathway when changing from M10 to M20 media.[202] FDA notes the following in the guidance:

> To be certain that a decision on when to submit a 510(k) is correct, one would probably need to enumerate all device types and all potential types of changes and then match each combination of device and change with a decision. Given that there are thousands of individual device types and possibly tens or hundreds of enumerable changes, this would be an impossible task. Furthermore, the resultant guidance would fill volumes, would probably be difficult to use, and would be unlikely to keep pace with an ever-changing technology.

There is more than one interpretation of the guidance on the need to submit a new 510(k) for the M10 to M20 change. One interpretation I have of the guidance flow charts is there is not a change of material type or formulation or supplier, as those decision points are described in the guidance, and no 510(k) is required. Another interpretation I have of the flow charts is there is a change in formulation and performance specifications of the material but indications are not changed and clinical data is not necessary, nor are there new issues of safety and effectiveness and again no 510(k) is required.

12. On page 24 Dr. David raises the issue of lack of validation of the 500 hour change in filter media. Dr. David does not assess the worst case conditions of use for filter efficiency, which is a new filter, or whether 500 hours of use can be adequately simulated. Mr. Zgoda testified as follows:[203]

> And I think the logic for me was that, you know, as filters get clogged they only get more efficient, they trap more particulate and so the interest would have been in is, you know, the filter so occluded that it affects the temperature

[202] FDA guidance K97-1, https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf.

[203] Zgoda deposition, 2/24/17, Page 148:25-149:6 and 149:24-150:10.

> Q. And then if we were to test a unit under the way Mr. Poppen's describing, we would have a better understanding of that issue, wouldn't we?...
> A. I guess I'm not sure I would agree with that because when you're -- if you want to run a unit for that amount of time, we have -- we would have a hard time recreating the environment used and actual facilities. So taking and putting it on a bench in a lab may not be indicative of what you would get in a a -- an account.

13. On page 24 Dr. David asserts the Model 750 was never tested or validated with respect to its effect on the operating room environment. I do not agree with this statement. It is my opinion that the safety aspects of the Model 750 questioned by Dr. David have been validated, in part, based on (1) publications including, for example, a government evaluation, (2) the independent evaluations by ECRI and The International Consensus Meeting on Periprosthetic Joint Infection in 2013, (3) the tested specifications of the M20 filter and its recommended use according to MERV standards, and (4) the clinical beta testing noted in the Design History File.

The 2010 letter to the editor by Memarzadeh at the National Institutes of Health concludes that FAW does not increase the risk of surgical site infection as follows:[204]

> NIH concludes that in both scenarios, there is zero percent deposition on the patient for the contaminant sources and the heat generated by the patient provides some protection. Although squames from the anaesthesiologist location move upwards due to thermal plume and away from the surgical site, supply flows largely dictate airflow pattern. When the forced-air warmer is operating, the downward velocity from ceiling laminar diffuser is slightly less strong than when it is off. With same supply air temperature, the air temperature around the surgical table is warmer when the forced-air warmer is operating. Forced-air warmers seem to cause minimal disruption to laminar airflow systems that help protect the surgical site from contaminated particles sourced from surgical staff.
>
> This investigation validates Moretti *et al.*'s conclusion that forced-air warming technology does not increase the risk of surgical wound infection. Further, if the operating room ventilation system is designed properly, contaminating particles from staff around the patient will not impinge on the surgical wound due to 'thermal plume' dynamics.

[204] 3MBH01630506-01630507.

The consensus in the 2013 Proceedings of the International Consensus Meeting on Periprosthetic Joint Infections report concludes that no studies have shown an increase in SSI related to FAW blankets as follows:[205]

Consensus: We recognize the theoretical risk posed by FAW blankets and that no studies have shown an increase in SSI related to the use of these devices. We recommend further study but no change to current practice.

The 2013 ECRI Institute Report concludes evidence does not support discontinuance of FAW devices as follows:[206]

CONCLUSIONS

Based on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods. Although one study (McGovern et al.) presents data that suggests higher PJI rates with use of FAW compared to an alternative warming method, this study has serious limitations such that its findings on PJI rates cannot be considered conclusive. Studies that look at FAW's contribution to OR air contamination and/or airflow disruption raise questions about the technology and its potential impact, but they do not provide sufficient evidence to demonstrate that the use of FAW poses a greater risk of SSIs or PJIs than the use of other warming methods.

Consequently, ECRI Institute does not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. We will continue to monitor this topic through the published literature and will update our recommendation as warranted.

[205] 3MBH01630605.

[206] 3MBH01630611.

The ECRI report also notes the following:[207]

ECRI Institute has learned that in March 2013, a lawsuit was filed against 3M Corporation alleging that a patient sustained a periprosthetic infection while undergoing hip replacement surgery as a result of contaminants being deposited in the surgical site by a 3M Bair Hugger forced-air warmer.

We have reviewed the plaintiff's petition. It does not present any new information that would alter the conclusions we have drawn in this article based on our review of the published literature.

My prior comments include my assessment of the M20 filter testing, specifications, and MERV rating with applications in health care facilities. Ms. Danielson testified as follows:[208]

A. The current filtra -- filtration levels -- The current filter I'm aware has been reviewed in terms of filtration levels expected for sort of the -- the hospital standards for operating rooms. And again I'm not a technical expert, but the -- the current -- the capacity of the current filter is equivalent to the standard for hospital operating rooms.

And I think in terms of the purpose of the filter for the device, as I understand it, that that would -- it's -- there's filtered air in the OR to begin with. If the device filter is at the same level of filtration as air coming into the OR, I think it would be reasonable to -- to conclude that that's an adequate level of filtration for that device to -- to not disrupt or not contribute to contamination.

14. On page 25 Dr. David again alleges that the company "secretly" made changes to the Model 505 filter. In this report I have previously commented on his inaccurate characterizations. The change in filter for the Model 505 in 2009 did not require a new submission to FDA. I have

[207] Id.

[208] Danielson 3/17/17, 90:4-19.

also referred to testimony why the actual filtration level was not disclosed. Contrary to Dr. David's impression, the document to which he refers contains a lot of suggested information to provide to customers, including that the filter is sub-HEPA.[209]

On page 25 Dr. David states that the hazard analysis needs to be updated when there is a change in the device's components and refers to the change requirements in the Quality System regulation, although he misstates the regulatory cite. The Standard Operating Procedures for Arizant included a Post-Production Risk Analysis Procedure that was periodically updated.[210] The procedure provides for post-production reviews in two-year intervals that include the review of various subjects such as Engineering Change Orders (ECOs) and Process Change Orders (PCOs). The 2016/2017 FMEA for the Model 505 and 750 indicates the potential hazard of surgical site infection and related risk/benefit. I do not believe that the surgical site hazard was a new hazard at any point of marketing of a Bair Hugger and based on the risk/benefit information accumulated over time the estimate of risk remains as is now documented in the 2016/2017 analysis.

15. On page 25 Dr. David begins a discussion of a 2009 FDA inspection of Arizant. Dr. David notes that the Establishment Inspection Report states that "The warming unit has a 0.2µm HEPA filter" which it did not.[211] As I note above in this report there is no deposition testimony that Arizant intentionally mislead the FDA inspector.

[209] 3MBH00132832.

[210] 3MBH02290521-02290565.

[211] 3MBH00048067-00048085.

He also questions the specific literature provided to the FDA inspector that is referenced in the EIR. Mr. Westlin testified that he supplied the literature that responded to the FDA inspector's request as follows:[212]

A. I'd have to look here and see if they were, but I don't remember they were. But the discussion was the allegations that they were dealing with and the discussion was about what evidence we had otherwise, and that's why we presented the evidence that we had that there was not a concern.

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Q. Okay. Now when you provided that literature that's listed here in the report, you would agree with me that that literature does not represent a fair totality of the literature on this issue of airborne contamination.

MR. SMITH: Objection to form.

MS. GARCIA: Join.

A. That's correct, but that's not what was asked for.

Dr. David refers to the inspector's statement on the lack of a procedure on environmental and contamination controls specific to microbial contamination. The EIR is unclear if there were no environmental and contamination control procedures whatsoever. In any case, the EIR does not include an observation pertaining to lack of environmental or contamination controls.

16. On page 26 Dr. David discusses what I call the nonsterile state of the Bair Hugger. Augustine Medical, Arizant and 3M never claimed in any labeling or advertising that any model of the Bair Hugger was sterile.[213] I am unaware of any warming device with a sterile labeling claim.

[212] Westlin deposition, 12/16/16, Page 143:3-8 and 144:6-14.

[213] Sterility is the absence of viable organisms.

So-called noncritical device surfaces, like those of the Bair Huggers, are recommended by FDA and CDC to be cleaned.[214] Dr. David notes that Bair Hugger instructions provide for external surface cleaning of the device. I am unaware of any electro-mechanical device placed outside the sterile field in an operating room with internal fan components to have sterilization or disinfection procedures for both external and internal surfaces.

17. On page 27 of his report Dr. David begins a section entitled "Review of Literature Finding Risk from the Use of the Bair Hugger." This section includes reference to 11 publications and two poster presentations. He states that "While the individual results of these studies are not definitive, collectively they support the conclusion that the Bair Hugger has the potential to cause surgical site infections in orthopedic surgeries."

Dr. David is a member of an FDA advisory committee. As such he should be aware of and consider the regulatory criteria by which FDA assesses data concerning the safety and effectiveness of medical devices for purposes of classification, clearance and approval. Criteria provided for the fair evaluation of all available evidence to render a decision on safety and effectiveness as follows:[215]

> "After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a

[214] FDA Disinfection and Sterilization Guidance, https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf and https://www.cdc.gov/hai/pdfs/disinfection_nov_2008.pdf.

[215] 21 CFR §§860.7(c)(1) and (c)(2).

whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use."

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Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.

Dr. David's analysis does not meet these criteria. He references only 13 publications and posters. In comparison, for example, the April 2013 ECRI analysis I reference above in this report began with an unbiased examination of 180 studies. ECRI's report details its analysis of four publications that Dr. David does not reference.[216]

It is my conclusion that Dr. David's assessment is not fair in that it does not render a conclusion based on analysis of the data as a whole by FDA's criteria.

18. On page 31 Dr. David begins a section entitled "Defendant's Refusal to Mitigate Patient Risk." He discusses "Project Ducky" and the evaluation of a silver coating on the interior of the hose.

He refers to a quote by Dr. Michelle Hulse-Stevens concerning a consensus meeting but does not provide the opinion of that consensus conference which stated:[217]

[216] Papers by Huang, Moretti, Melling, and McGovern.

[217] 3MBH01630605.

Consensus: We recognize the theoretical risk posed by FAW blankets and that no studies have shown an increase in SSI related to the use of these devices. We recommend further study but no change to current practice.

He notes a quote from a document relating to the cost of a HEPA filter but does not include the entire quote in the same document that states the current filter is effective, as follows:[218]

Sorry also for the delay. Our filter description is a "high efficiency, 0.2 micron filter". It does not carry the HEPA designation. This is principally due to the added cost. We have studied this, as well as others in independent studies that have found that our current level of filtration is very effective.

I discuss Project Ducky and the antimicrobial coating in a prior opinion. Dr. David describes a 3M document on Blower Hose Ideation that does not comport with any notion that 3M/Arizant was unresponsive to customer input.[219] Rather, the ideations and other activities are indicative of Arizant's active design process taking into account customer input and competing designs. The ideations depicted in the drawings Dr. David displays were in response to marketing factors, not patient risk. . Winston Tan, a manager in the engineering group, testified as follows regarding the ideations:[220]

Q. Can you kind of describe what this document is for me.

A. Sure. In 2014 we were at the beginning stages of developing a new warming unit, and these were exploratory, some ideas, if we wanted to use some of the ideas on the new warming unit.

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[218] 3MBH00024682.

[219] 3MBH00630074.

[220] Winston Tan deposition, 3/10/17, Pages 104:12-17 and 105:1-7.

Q. Why was it important to keep the hose clean?
A. Just for the competitive landscape. We had some competitors out there that had a covering over the hose, and we were -- we were just looking at, when we did work on a new warming unit, these were some ideas that if --
These are features, competitive features.

Since what is represented by the ideation drawings are concepts at the very earliest stages, it is far from established that any of these concepts would be practicable and could be implemented.

In Section 8 Dr. David discusses his opinions regarding alternative devices. FDA has found other device technologies substantially equivalent, but FDA's findings do not render the other devices safer and FDA continues to permit the Bair Huggers to be marketed.

Dr. David speculates that the VitaHeat, Tableguard and Mistral-Air devices are safer. It is interesting that Dr. David does not identify the Augustine Medical Hot Dog as a safer device. These devices may have some different features compared to the Bair Hugger devices but different features present new hazards as is the case with the complaints for the Hot Dog device I discuss in this report..

I believe conclusions on comparative safety must be based on a complete comparative analysis of risks and benefits, complaints, all the relevant literature, independent third-party assessments, and the FDA recall and MAUDE databases to name a few sources of information.

VIII. SUMMARY REBUTTAL OF DR. DAVID'S LEGAL CONCLUSIONS AND RESPONSE TO PLAINTIFFS APRIL 2017 CONCLUSIONS

Summary Rebuttal of Dr. David's Legal Conclusions

Dr. David states that the Bair Hugger devices are not safe and adequately labeled, 3M/ Arizant did not meet good manufacturing practices and postmarket surveillance requirements, and the device is an unreasonable danger in the orthopedic operating rooms (Summary, Page 42-44). These allegations relate to violations of the prohibited acts of adulteration and misbranding.[221]

For eight years, from 2003 until 2011, I was the most responsible person in the FDA Center for Devices and Radiological Health for determining whether a medical device violated the laws and regulations FDA administers. I evaluated the evidence to determine whether the evidence supported bringing charges in the form of Warning Letters or enforcement actions. If I found the evidence insufficient I had the responsibility and authority to reject any or all advisory or enforcement actions.

The finding of a violation of the Act or regulations is ultimately a conclusion affirmed by a court. So-called FDA Warning Letters are advisory actions that are not final agency actions and FDA cannot be sued on their content.[222] Opinions of violations expressed in reports such as Dr. David's are not subject to the same legal scrutiny and due process occurring in the regulatory space.

In my opinion there is lack of evidence produced in Dr. David's report to support his assertion that the company acted in violation of the Act pertaining to the Bair Hugger, and that the Bair Hugger is adulterated or misbranded, as those prohibited acts and conditions are defined

[221] 21 USC Section 331.

[222] See FDA Regulatory Procedures Manual.

and described in Sections 331 (as well as 351 and 352) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.).

All the Bair Hugger devices were either cleared by FDA or are minor modifications of cleared devices. FDA's order finding these devices to be substantially equivalent provides reasonable assurance that they are safe and effective unless and until FDA considers them adulterated or misbranded.

There is lack of evidence produced in Dr. David's report that the Bair Hugger was adulterated under Section 351(h) of the Act pertaining to the Quality System (aka GMP) regulation as Dr. David claims. I refute his specific assertions in my report and detail, for example, the company's compliant design, complaint handling and reporting activities. FDA has inspected the company facilities multiple times, including for reasons related to Dr. David's assertions, the last time in late 2016, and has never taken an enforcement action against the company (i.e., Arizant or 3M, or the devices known as models of the Bair Hugger.[223] The company corrected to FDA's satisfaction all observations made during inspections and in Warning Letters.

As I have opined in this report the labeling for the Bair Hugger is not misbranded as Dr. David claims. FDA has never documented an observation in an inspection stating the labeling is deficient. All 510(k)s included labeling that was evaluated by FDA.

None of the literature evaluated by Dr. David attests to even one surgical site infection (SSI) that has been confirmed as caused by the Bair Hugger Model 750 or to any other Bair Hugger devices.[224] Prior to recent litigation there were few complaints submitted to FDA for

[223] Past Audit Documents 3MBH015157606-01789042. The Quality System regulation encompasses issues discussed by Dr. David, for example, complaint handling, corrective and preventive action, verification and validation and design control.

[224] Publications from 1987-2016.

Bair Hugger devices. FDA investigated Arizant's reporting procedures and decisions during inspections.

I have refuted his allegations regarding the filter used in the Model 505 and 750 and the company's transparency with FDA regarding the filter.

In a report published in April 2013 an independent test organization, ECRI, published its review of forced air warming and SSIs.[225] Their conclusions are supportive of the Bair Hugger devices and state as follows:

CONCLUSIONS

Based on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods. Although one study (McGovern et al.) presents data that suggests higher PJI rates with use of FAW compared to an alternative warming method, this study has serious limitations such that its findings on PJI rates cannot be considered conclusive. Studies that look at FAW's contribution to OR air contamination and/or airflow disruption raise questions about the technology and its potential impact, but they do not provide sufficient evidence to demonstrate that the use of FAW poses a greater risk of SSIs or PJIs than the use of other warming methods.

Consequently, ECRI Institute does not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. We will continue to monitor this topic through the published literature and will update our recommendation as warranted.

[225] Health Devices, April 2013, ECRI.

Confidential Under Protective Order

In sum, it is my opinion that the devices collectively known as the Bair Hugger meet the statutory and regulatory standard of reasonably safe and effective devices. Furthermore, they meet all relevant industry safety standards as evidenced by their verifications and validations and repeated certifications to safety standards by independent test laboratories.

Summary Statement Regarding Plaintiffs' Conclusions of April 2017

Plaintiffs have presented a list of conclusions in a motion filed on April 21, 2017. My report addresses the conclusions as follows:

1. 3M/Arizant conducted safety testing for the Bair Hugger as I describe in my analysis of the Bair Hugger 510(k)s and other comments regarding device testing. The devices were properly validated.

2. 3M/Arizant modified the efficiency of the Bair Hugger Model 750 based on performance requirements but still keeping the filter at an efficiency level consistent with hospital industry standards as I describe in my report. The company did not hide the filter specifications for the Bair Hugger Models 505 or 750 from FDA.

3. The Bair Hugger is a nonsterile device and therefore its surfaces are not free from potentially viable microorganisms. 3M/Arizant makes no claim that the Bair Hugger is sterile. All other warming devices with or without HEPA filters also cannot claim their devices to be sterile.

4. 3M/Arizant evaluated design changes to the Bair Hugger to respond to customer inputs as I describe in my report, and the company did not adopt the changes I describe in this report for valid scientific reasons.

5. 3M/Arizant has not disregarded complaints regarding its devices as I describe in this report. I defer in-depth analysis of tests, research and the literature to other Defendant experts.

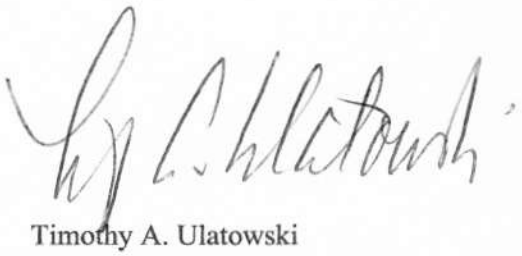
6. 3M/Arizant has communicated its assessment of the literature relevant to the issues in this litigation to FDA. An independent organization assessed all the relevant literature as I describe in this report. Plaintiff's expert I rebut assessed limited, selected literature in a comparably less than fair and thorough manner.

7. I defer to other witnesses on the Plaintiff's conclusion regarding manipulation of certain research.

8. I defer to other witnesses on the Plaintiff's conclusion regarding suppression of testing.

9. Defendant produced compliant labeling according to federal statute and regulations. All labeling for the Bair Hugger was examined by FDA multiple times in a succession of premarket submissions. The labeling includes instructions for use information as required.

I may supplement my report based on new information produced in this litigation.



Timothy A. Ulatowski

Dated: June 2, 2017